2-(2,4,5-trichlorophenoxy) Propionic Acid (Silvex)

Notice of Intent to Cancel Certain Registrations of Pesticide Products Containing Silvex

I. INTRODUCTION

I am today issuing an emergency order suspending immediately the forestry, rights-of-way, pasture, commercial/ornamental turf, home and garden, and aquatic weed control/ditch bank uses of pesticide products containing silvex, and a statement of reasons. Section 6(c)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) [7 U.S.C. Section 136d(c)(1)] provides that a suspension order cannot be issued unless a notice of intent to cancel the registrations or change the classifications of the pesticide products concerned has already been issued or is issued with the suspension order. For the reasons set forth below, I find that forestry, rights-of-way, pasture, commercial/ornamental turf, home and garden, and aquatic weed control/ditch bank uses of pesticide products containing silvex, in accordance with current use instructions, appear to pose an unreasonable risk to humans. I am therefore announcing my intention to cancel all these registered uses of silvex under Section 6(b) of FIFRA [7 U.S.C. Section 136(d)(b)].

-- LEGAL AUTHORITY

Section 6(b) of FIFRA [7 U.S.C. Section 136d(b)] horizes the Administrator to issue a notice of intent cancel the registration of a pesticide or to change classification if it appears to him that the pesticide

or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Thus, the Administrator may cancel the registration of a pesticide whenever he determines that it no longer satisfies the statutory standard for registration which requires (among other things) that the pesticide "perform its intended function without unreasonable adverse effects on the environment" [FIFRA Section 3(c)(5); 7 U.S.C. Section 136a(c)(5)]. He may also change the classification of any use of a pesticide if he determines that such a change "is necessary to prevent unreasonable adverse effects on the environment" [FIFRA Section 3(c)(2); 7 U.S.C. Section 136a(d)(2)]. "Unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [FIFRA Section 2(bb); 7 U.S.C. Section 136(bb)].

The burden of proof for establishing the safety of a pesticide product to support a decision concerning registration or continued registration rests at all times on the proponent of registration [Environmental Defense Fund v. Environmental Protection Agency, 465 F.2d 528, 532 (D.C. Cir. 1972); EDF v. EPA, 510 F.2d 1293, 1297 (D.C. Cir. 1975); EDF v. EPA, 548 F.2d 998, 1004 (D.C. Cir. 1976)].

In effect, FIFRA requires the Administrator to weigh the risks and benefits associated with each use of a pesticide. If he determines for any particular use that the risks exceed the benefits, he must then determine whether those risks can be sufficiently reduced (so that they are outweighed by the benefits) by the imposition of restrictions upon use through changes in the labeling and/or by the classification of the use for restricted use. If he determines that adequate risk reduction cannot be achieved by such regulatory measures, the registration of the pesticide for that use must be fully cancelled.

III. REASONS FOR INITIATING PROCEEDINGS TO CANCEL

A. Risks

On the basis of data available to the Agency, I conclude that silvex and/or its contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), create a serious health risk for humans and that human exposure to silvex and/or its contaminant, TCDD, is cause for considerable concern.

The Agency has reviewed numerous studies in which industrial, academic, and government scientists have reported that TCDD and/or silvex contaminated with TCDD produce fetotoxic, teratogenic, and carcinogenic effects in test animals that have been exposed to these chemicals. The occurrence of these adverse effects in test animals following exposure to silvex and/or TCDD indicates that humans who are exposed to silvex may experience comparable effects.

Concern for the health of humans who may be exposed to TCDD, and therefore silvex contaminated with TCDD is heightened because scientists have not demonstrated that there is a level of exposure that has no adverse effects in humans.[1/]

A recent EPA-sponsored epidemiological study shows human miscarriages to be related both geographically and temporally to the use of 2,4,5-T (a chlorophenoxy herbicide closely related to silvex, and which also contains TCDD). Specifically, the study indicates that women who live in an Oregon area (Study area) where 2,4,5-T is used for forest management experience miscarriages more frequently than do women who live in other Oregon areas where there is little or no known use of 2,4,5-T or other dioxin-containing phenoxy herbicides. Most significantly, the data generated through this study show that the increase in frequency of miscarriages for women in the Study area is greatest two months after the period when 2,4,5-T is used in this area, and that there is a close correlation between the amount of 2,4,5-T used by month and the size of the increase in the frequency of miscarriages two months later. Information has recently become available to the Agency which documents the use of silvex in the Alsea area during the period of time

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1/ A Committee of the National Research Council of Canada recently agreed with the authors of the World Health Organization's monograph on TCDD that "for TCDD a no-effect level for man could not be established" (NRCC 1978).

studied. However, even without this information, I would have found that the serious implications of this study are as applicable to silvex as to 2,4,5-T. TCDD, the contaminant contained in both herbicides, is a potent mammalian fetotoxin and teratogen at very low doses. Conversely, silvex and 2,4,5-T are fetotoxic and teratogenic at comparatively high doses. It is reasonable to assume that the adverse human reproductive effects observed in Alsea which have been attributed to low-level exposure to 2,4,5-T are due primarily to the TCDD in 2,4,5-T. Therefore, since silvex also contains TCDD, I conclude that the Alsea data are applicable to areas where silvex is used when evaluating potential reproductive risk to humans.

I also conclude that it is prudent to assume that individuals living in or frequenting areas where the forestry use of silvex occurs may experience exposure to TCDD qualitatively similar to that experienced by the Alsea women and may suffer the adverse effects which silvex, 2,4,5-T, and/or TCDD produce. I further conclude that individuals, living in or frequenting areas where the use patterns of silvex create similar or greater possibilities for exposure than the forestry use, have a potential risk of adverse effects from silvex exposure. A comparable risk potential is applicable to persons who are occupationally exposed to silvex through these uses. Such use patterns

include, without necessarily being limited to, the rights-of-way and pasture uses of silvex. Additional uses of silvex (home and garden, aquatic weed control/ditch bank, and commercial/ornamental turf uses) are comparable to uses of 2,4,5-T cancelled or suspended in 1970 because of concern that exposure to 2,4,5-T and/or TCDD posed an imminent hazard to humans and to the environment. Because silvex also contains TCDD, I conclude that it is prudent to take similar action for these silvex uses. The Agency has identified pesticide applicators and persons involved in pesticide application support activities, and persons living in or frequenting areas of silvex use as the principal groups of individuals who may be exposed as a result of the forestry, right-of-way, pasture, home and garden, aquatic weed control/ditch bank, and commercial/ornamental turf uses of silvex. Based upon animal data and other information (including the recent Oregon study), individuals exposed to silvex may suffer adverse reproductive effects or develop cancer.

B. Determination of Benefits

The Agency has evaluated the economic effects of cancelling non-crop uses of silvex. The non-crop uses of silvex include those it has in common with major uses of 2,4,5-T (forestry, pasture, and rights-of-way), as well as turf (home and garden and commercial/ornamental turf) and aquatic weed control/ditch bank uses.

Domestic usage of silvex is estimated to be about 2.8 to 3.3 million pounds annually. Commercial/ornamental turf and home and garden uses of silvex are the largest volume uses, comprising more than 50% of domestic usage. Aquatic weed control/ ditch bank usage account for about 8% of annual usage. Other uses, primarily pasture, account for about 10% of use. The uses of silvex subject to this cancellation notice account for about two-thirds of its annual usage.

The Agency's analysis indicates that cancellation of silvex non-crop uses would not significantly affect U.S. production or prices of any commodities or services in affected sectors. Economic impacts of the cancellation would be minor in most cases, even at the local/regional level. The major significance of cancelling silvex is that it would not be available to replace 2,4,5-T on forest and pasture sites.

The economic impacts of cancelling each of the non-crop uses of silvex are discussed below.

(1) Forestry

The cancellation of forestry uses of silvex would not have any significant economic impact because the chemical is not now in use. The principal potential users, the Department of the Interior (USDI) and the U.S. Forest Service (USFS), have already discontinued use. The significance of the silvex cancellation for forestry use is that it

would not be available as a substitute for 2,4,5-T. However, silvex is not an acceptable substitute for 2,4,5-T on many acres because it is toxic to pines. Thus, impacts would be limited to non-pine Western conifer forests and some Northeastern fir spruce stands.

Silvex has been used in forestry mostly by the U.S. Department of the Interior, on parts of approximately 2 million acres of Bureau of Land Management (BLM) lands; lesser amounts have been used by the USFS. Silvex is used prior to planting for site preparation and later to assist growth of young trees by "releasing" them from competing hardwood trees and brush.

There are many alternatives to silvex for site preparation. Several chemicals (2,4-D, picloram, Atrazine, Banvel, and dicamba), as well as mechanical methods, controlled burning, and combination methods, may be effectively used for this purpose.

Release of young conifers requires a selective herbicide or manual methods to reduce hardwood competition. Silvex, 2,4,5-T, and 2,4-D are the only Federally registered chemicals providing this selective control. Silvex and 2,4,5-T are preferred because 2,4-D controls a more limited spectrum of woody species.

Silvex is not widely used in forest site preparation/ release activities. So far as is known, the only extensive recent use of silvex has been by BLM in western Oregon.

However, BLM has used no herbicides since 1977. The USFS treated approximately 2,700 acres of forest lands with 1,750 lbs of silvex in 1977. USDI is presently considering prohibiting the use of silvex. Plans have been developed for vegetation management without silvex.

(2) Rights-of-Way

The economic impact of cancellation of the use of silvex on rights-of-way would be minimal. Chemical, manual, and mechanical methods are used on highway, electric, railroad, and pipeline rights-of-way acres to control woody and herbaceous plants that would otherwise impede the use of equipment, interfere with inspection and maintenance and in extreme situations interfere with the functioning of the right-of-way system.

Manual and mechanical methods are the most common control practices on rights-of-way acreage. Present usage of silvex for rights-of-way vegetation control is minimal, e.g., less than 2% of rights-of-way firms use it. If silvex were not available, users could treat with other herbicides. Dichloroprop, 2,4-D, and picloram mixed with 2,4-D are all cheaper than silvex, and in some instances are more effective.

(3) Pasture

The phenoxy herbicides (2,4-D, 2,4,5-T and silvex) are registered for the control of many woody and herbaceous

weeds on pasture.[2/] Silvex is generally more effective for woody plant control than 2,4-D, but less effective than 2,4,5-T. No more than 250,000 lbs of silvex are used on pasture acreage each year.

Other chemicals, such as pelleted formulations of picloram, dicamba, 2,4-D are generally preferred to silvex for pasture use. Therefore, farmers who currently use silvex would turn to these alternative herbicides. The use of alternatives would prevent reductions in yield or production. Therefore, there would be no impact on consumer prices or the general economy. Agricultural income may be reduced by an immeasurably small amount.

(4) Commercial/Ornamental Turf

Silvex is used on various types of commercial and ornamental turf, such as golf courses, athletic fields, parks, playgrounds, highway turf, and turf farms. Golf courses are the principal use. Annual usage could be as much as 2 million pounds of active ingredients.

Effective alternatives are available. Among them are 2,4-D, MCPP, and dicamba. Use of alternatives could increase costs by about $3.50/acre. However, the use of these more expensive alternatives would not add substantially

2/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

to overall turf maintenance costs in most situations. For example, turf maintenance for golf courses now costs approximately $80-90 per acre. Thus, the economic impact of cancelling silvex use would not be highly significant.

(5) Home and Garden

Several hundred thousand pounds of silvex are used per year on home lawns and garden areas. Most of the herbicides used by homeowners in the U.S. are for control of broadleaf weeds and grass pests in lawns. However, most homeowners do not use any herbicides.

Several equally efficaceous alternatives to silvex are available and comparable in cost. Homeowners could shift to products containing 2,4-D, MCPP, and dicamba without experiencing inconvenience. Thus, homeowner impacts stemming from cancellation would be negligible.

(6) Aquatic Weed Control/Ditch Bank

Aquatic weeds are a nuisance in water bodies used for recreation and in farm ponds used for watering livestock. Major uses of herbicides for aquatic weed control are government and private recreational organizations and farmers. Economic effects of cancelling aquatic/ditch bank uses of silvex would be nominal because effective, economical alternatives (2,4-D, diquat, endothall, dichlobenil, and biological controls) are generally available.

C. Conclusion

On the basis of information currently available, I conclude that the risks posed by the continued use of silvex on forests, rights-of-way, pastures, homes and gardens, commercial/ornamental turf and aquatic weed control/ditch bank areas in accordance with current terms and conditions of registrations and commonly recognized practice appear to outweigh the benefits of these uses. For these reasons, I conclude that these uses of silvex appear to generally cause unreasonable adverse effects on the environment [see FIFRA Section 2(bb)] when used in accordance with widespread and commonly recognized practice. Accordingly, I am hereby initiating proceedings to cancel the registrations of all pesticide products containing silvex registered for forestry, rights-of-way, pasture, home and garden, commercial/ornamental turf and aquatic weed control/ditch bank uses.

IV. PROCEDURAL MATTERS

This Notice initiates an action to cancel the registrations of the forestry, rights-of-way, pasture, home and garden, aquatic weed control/ditch bank, and commercial/ornamental turf uses of silvex.[3/] Under Section 6(b) and 3(c)(6) of FIFRA [7 U.S.C. 136d(b); 7 U.S.C. 136b(a) (c)(5)] registrants and other interested

3/ Other procedural matters relating to the emergency actions are presented in the accompanying order suspending the uses in question.

persons may request a hearing on the cancellation actions that this Notice initiates. This section explains the prohibition against ex parte communications, when and how affected persons may request a hearing, and the consequences of filing or of failing to file a request for a hearing in accordance with the procedures specified in this Notice.[4/]

A. Ex Parte Communications

The Agency's Rules of Practice for hearings conducted pursuant to Section 6 of FIFRA forbid the Administrator, the Judicial Officer, and the Administrative Law Judge, at all stages of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation of presentation of the proceeding as an advocate or in an investigative or expert capacity, or with any of their representatives. (40 CFR Section 164.7).

Accordingly, the following Agency officers, and the staffs thereof, are designated to perform all investigative and prosecutorial functions in this case: the Office of

4/ Although Section 6(b) of FIFRA generally requires prior review of and comment upon proposed notices of intent to cancel or change classification by the Secretary of Agriculture and a Scientific Advisory Panel, I am specifically authorized to waive such requirements and proceed in accordance with Section 6(c) of FIFRA whenever I find that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health. I have found that immediate suspension of the registrations of pesticide products containing silvex is necessary to prevent an imminent hazard to human health (see Emergency Suspension Order and Notice of Intent to Suspend Uses of Silvex, issued this day). I hereby invoke my authority to waive the external review requirements.

Toxic Substances, the Office of Pesticide Programs, the Office of General Counsel, and the Office of Enforcement.

From the date of this notice until any decision, neither the Administrative Law Judge, the Judicial Officer nor myself shall have any ex parte contact or communication with any investigative or trial staff employee, or any other interested persons not employed by EPA, on any of the issues involved in this proceeding. However, persons interested in this case should feel free to contact any other EPA employee, including both investigative and trial staff, with any questions they may have.

B. Procedures for Requesting a Hearing

(1) When a Hearing Must be Requested for Cancellation Actions

Registrants affected by cancellation actions initiated by this Notice may request a hearing within 30 days of receipt of this notice, or within thirty days of the date of publication of this notice in the Federal Register whichever occurs later. Any person adversely affected by the cancellation actions initiated by this Notice may request a hearing within thirty days of the date of publication of this Notice in the Federal Register.

(2) How to Request a Hearing

All registrants and other interested persons who request a hearing must follow the Agency's Rules of Practice Governing Hearings (40 CFR, Part 164). These procedures

specify, among other things, that: (1) all requests for a hearing must be accompanied by objections that are specific for each use for which a hearing is requested [40 CFR 164.20(b)], and (2) that all requests must be received by the Hearing Clerk within the applicable thirty (30) day period [40 CFR 164.5(a)]. Failure to comply with these requirements will automatically result in denial of the request for a hearing.

Requests for hearings must be submitted to:

Hearing Clerk (A-110)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

C. Consequences of Filing or Failing to File a Hearing Request

If a hearing is requested on any cancellation action on a silvex use initiated by this Notice before the end of the 30-day notice period, the hearing will be governed by the Agency's rules of practice for hearings under FIFRA Section 6 (40 CFR, Part 164). In the event of a hearing, the cancellation action(s) subject to the hearing will not become effective except pursuant to orders of the Administrator at the conclusion of the hearings.

Date: FEB 28 1979

Douglas Costle
Administrator

DECISION AND EMERGENCY ORDER SUSPENDING REGISTRATIONS FOR CERTAIN USES OF 2-(2,4,5-TRICHLOROPHENOXY) PROPIONIC ACID (SILVEX)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D. C. 20460

Office of Pesticide Programs
February 28, 1979

Suspension Order

Registrations issued under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. Section 136 et., seq. of all pesticide products containing 2-(2,4,5-trichlorophenoxy) Propionic Acid (Silvex) for the forestry uses (including site preparation, conifer release, and brush and weed control), rights-of-way uses (including brush and weed control), pasture uses*/, home and garden uses, commercial/ornamental turf uses (including recreational area uses), and aquatic weed control/ditch bank uses are hereby suspended and the sale, distribution, or other movement in commerce, and the use of all such pesticide products for the foregoing uses is prohibited.

Douglas M. Costle
Administrator

Date: FEB 28 1979

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*/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

Decision and Emergency Order Suspending Registrations for Certain Uses of 2-(2,4,5-Trichlorophenoxy) Propionic Acid (Silvex)

I. INTRODUCTION

During the past two years, the Agency has been gathering information about the closely related phenoxy herbicides, 2-(2,4,5-trichlorophenoxy) propionic acid (silvex) and 2,4,5-trichlorophenxoy acetic acid (2,4,5-T), as part of its Rebuttable Presumption Against Registration (RPAR) process in order to decide whether the registration of this pesticide should be continued. This review was prompted by studies showing that silvex, 2,4,5-T, and/or their dioxin contaminant, 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD)*/, caused reproductive and oncogenic effects in test animals. During the public debate initiated by the 2,4,5-T RPAR (43 FR 17116, April 21, 1978), the Agency received reports that women living in the vicinity of Alsea, Oregon, had miscarriages shortly after 2,4,5-T was sprayed in the forest areas where they reside. The Agency investigated the circumstances surrounding these reported miscarriages

*/ Current methods for manufacturing silvex produce TCDD as a by-product of the manufacturing process. Although silvex manufacturers attempt to remove this contaminant, TCDD cannot be completely removed. An EPA contract laboratory has measured the TCDD content in 8 recently produced commercial samples of technical grade silvex from two different manufacturers. The contractor reported that the TCDD content in these samples ranged from 0.012 to 0.024 ppm TCDD (limit of detection: 0.01 ppm). Therefore, because TCDD is present as a low-level contaminant in commercial samples of silvex, references in this document to "silvex" or the "pesticide product" mean silvex that is contaminated with TCDD.

and compared the frequency of miscarriage in the Alsea area with comparable data from a control area. The Agency has concluded that the use of 2,4,5-T over a six-year period in the Alsea area was related to a statistically significant increase in the frequency of miscarriages by women residents of the area, and that these miscarriages occurred shortly after the use of 2,4,5-T in the area where these women resided.

Based on this and other information, I am ordering several emergency suspensions under FIFRA Section 6(c), which halt the distribution, sale, and use of 2,4,5-T for forestry, rights-of-way, and pastures**/ until the completion of further administrative proceedings.*/ Because both silvex and 2,4,5-T are contaminated with TCDD, and because of similarities in chemical structure, manufacturing processes, use patterns, and effects in experimental systems, I consider it prudent to take similar regulatory action against silvex. I am therefore ordering emergency suspension of the forestry, rights-of-way, and pasture uses of silvex because I find that they pose an "imminent hazard" to humans and to the

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**/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

*/ For details, see the risk discussion in Section IV of this document and the 2,4,5-T suspension document, published simultaneously with this document.

environment; I also find that an "emergency" exists because there not enough time to hold a suspension hearing before the next spraying season.

In addition, I am ordering the emergency suspension of the home and garden, aquatic weed control/ditch bank, and commercial/ornamental turf uses of silvex. These additional uses of silvex are comparable to uses of 2,4,5-T cancelled or suspended in 1970 because of concern that exposure to 2,4,5-T and/or TCDD posed an imminent hazard to humans and to the environment. I now make similar findings of imminent hazard for these uses of silvex. I also find that an emergency exists relative to these uses because there is not enough time to hold a suspension hearing before the spring and early summer period of major silvex application for home and garden, aquatic weed control/ditch bank, and commerical/ornamental turf uses. In addition, I find that the year-round application of silvex in certain areas of the country adds to the urgency of the situation for the home and garden and commercial/ornamental turf uses.

II. LEGAL AUTHORITY

A. Standards for Maintaining a Registration

In order to obtain a registration for a pesticide under FIFRA, a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires (among other things) that the pesticide

perform its intended function without "unreasonable adverse effects" on the environment [FIFRA Section 3(c)(5)]. "Unreasonable adverse effect on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [FIFRA Section 2(bb)]. In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of the use. The burden of proving that a pesticide satisfies the registration standard rests with the registrant and continues for as long as the registration remains in effect [Environmental Defense Fund v. Environmental Protection Agency, 510 F.2d 1292, 1297 (D.C. Cir., 1975); Environmental Defense Fund v. Environmental Protection Agency, 465 F.2d 528, 532 (D.C.Cir., 1972)]. Under Section 6 of FIFRA, the Administrator is required to cancel the registration, or change the classification, of a pesticide whenever he determines that the pesticide no longer satisfies the statutory standard for registration.

B. Purpose and Standard for Suspending a Pesticide

The suspension provisions in Section 6(c) of the statute give the Administrator authority to take interim action until completion of the time-consuming procedures required to reach final cancellation decisions. Under this Section, the Administrator may suspend the registrations of a product and prohibit its distribution, sale, or use during cancellation proceedings upon a finding that the pesticide

poses an "imminent hazard" to humans or the environment. "Imminent hazard" is defined by the statute to mean that:

> The continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 94-135.

As discussed above, "unreasonable adverse effects on the environment" means that the risks from use of a pesticide outweigh the benefits of its use. Thus, in order to find an imminent hazard, it is necessary to find that the risks of use during the period likely to be required for cancellation proceedings appear to outweigh the benefits. The Administrator may not suspend a pesticide without having issued a notice of his intention to cancel the registration, or to change the classification, of the pesticide.

Suspension is the Administrator's tool for quickly correcting a situation which endangers public health. The courts have repeatedly held that "the function of a suspension decision is to make a preliminary assessment of evidence, and probabilities, not an ultimate resolution of difficult issues" [Environmental Defense Fund v. Environmental Protection Agency, supra, 510 F.2d at 1298]. "It is enough if

there is a substantial likelihood [emphasis in original] that serious harm will be experienced during the year or two required in any realistic projection of the administrative (cancellation) process" [Environmental Defense Fund, Inc. v. Environmental Protection Agency, 510 F.2d 1292, 1297, (D.C. Cir. 1975) quoting from Environmental Defense Fund, Inc. v. Environmental Protection Agency, supra, 465 F.2d 540 (D.C. Cir. 1972)]. Moreover, the registrant bears the burden of proof during a suspension proceeding because, as indicated above, the burden of proof under FIFRA always resides with the proponent of registration throughout the life of a registration. (See, e.g., Environmental Defense Fund v. Environmental Protection Agency, 510 F.2d at 1297; Environmental Defense Fund v. Environmental Protection Agency, supra, 465 F.2d at 532.)

C. Types of Suspension Proceedings

In this order, I have begun emergency suspension proceedings. This is not the only type of suspension provided in FIFRA. Section 6(c) provides for two kinds of suspension proceedings: ordinary suspensions [FIFRA Section 6(c)(2)] and emergency suspensions [FIFRA Section 6(c)(3)]. I have chosen to discuss both kinds of suspension because the procedures applicable to each action are intertwined and because of the complexity of the suspension provision as a whole.

(1) Ordinary Suspensions

The Administrator may begin an ordinary suspension when he finds that action is required to prevent an "imminent hazard." An ordinary suspension is not effective immediately; instead, the Administrator is required to give registrants notice of his intent to suspend and to allow five days for them to request a hearing. Only a registrant may request a hearing. If a hearing is not requested within five days, the suspension order becomes final and is not reviewable by a court. If a hearing is requested, the Administrator is required to convene an expedited proceeding at which other interested persons can intervene. The sole issue at a hearing is whether an imminent hazard in fact exists. The procedures for conducting the hearing, with limited exceptions discussed below, parallel the hearing procedures for an emergency suspension. The Administrator decides whether to affirm his imminent hazard determination at the conclusion of the hearing; if he does, he issues a suspension order. This order is accompanied by a notice of intent to cancel the registration, or to change the classification, of a pesticide (if one has not previously been issued). A final order on suspension following a hearing is reviewable in the Court of Appeals.

(2) Emergency Suspensions

Before issuing an emergency suspension order, the Administrator is required to make two findings: (1) that

the pesticide poses an "imminent hazard" and (2) that an "emergency" exists. An "emergency" exists when the situation "does not permit [the Administrator] to hold a hearing before suspending" [FIFRA Section 6(c)(3), 7 U.S.C. 136d(c)(3)]. The Agency interprets this statutory provision to mean that, if the threat of harm to humans and to the environment is so immediate that the continuation of a pesticide use is likely to result in unreasonable adverse effects - i.e. the risks outweigh the benefits - during a suspension hearing, the registration of any product for that use may be suspended immediately*/.

An emergency suspension order is issued without prior notice to registrants and takes effect immediately; it remains in effect until the cancellation decision if no expedited hearing is requested. If an expedited hearing is requested on the issue of imminent hazard, the emergency order continues in effect until the issuance of a

*/ The term "emergency" is not defined by FIFRA, and the statute in the emergency suspension section does not specifically require the Agency to balance benefits against health and environmental risk of pesticide use. An alternative reading would be that an emergency exists whenever a serious risk could result from pesticide use during the time for conducting a suspension hearing. However, for the purpose of this proceeding I have decided to consider the risks and benefits in ordering an emergency suspension, just as I balance risks and benefits in deciding whether to register a pesticide or to take the pesticide off the market through a cancellation or ordinary suspension order. FIFRA is a risk/benefit statute, and I see no reason to depart from this balancing test in issuing emergency suspension orders.

final suspension order. Registrants are given five days to request an expedited hearing. The hearing stage is to begin within five days of the Agency's receipt of the hearing request. Unlike the ordinary suspension situation, no party other than the registrant and the Agency may participate in the expedited hearing on the emergency order, except to file briefs. The procedures for conducting the hearing are otherwise the same as in an ordinary suspension. For both types of suspension, the hearing is to be conducted in accordance with 5 U.S.C. Section 554.556 and 557 except that the presiding officer need not be a certified hearing examiner. For both types of suspension, the presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator. The Administrator shall then have seven days to issue a final order on the issue of suspension.

FIFRA provides for a special appeal of an emergency suspension order to the District Court. If an administrative hearing is requested, an emergency suspension order is subject to immediate review in District Court by the registrant or by other interested persons with the registrant's consent. On the other hand, if no request for a hearing before the Agency is made, the emergency order becomes final and is not reviewable by any court [FIFRA Section 6(c)(2), 6(c)(3)]. The District Court action may occur

simultaneously with the suspension proceeding before the Administrator.

The District Court reviews only whether the emergency finding is supported. The standard for review by the District Court is very narrow--whether the order of suspension is "arbitrary, capricious, or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law" [FIFRA Section 6(c)(4)]. If the District Court finds against the Agency, it may stay the suspension order until completion of the expedited suspension hearing.

The District Court order may be appealed to the Appellate Court by either the Agency or the registrant, depending on the outcome. A final order on suspension, after a hearing before the Agency, may be reviewed in the Court of Appeals on an expedited basis even though related cancellation proceedings may not have been completed.

III. SUMMARY OF FINDINGS

A. Summary of Findings on Risk

Numerous studies have clearly demonstrated that TCDD and/or silvex contaminated with TCDD can produce fetotoxic, teratogenic, and carcinogenic effects in experimental animals which have been exposed to these chemicals. I find that the occurrence of these effects in test animals indicates that humans who are exposed to TCDD and/or silvex may experience comparable effects.

A recent epidemiological study reported that women living in the vicinity of Alsea, Oregon (an area where 2,4,5-T and silvex were extensively used),*/ have a statistically significant higher incidence of spontaneous abortions (miscarriages) than women living in a control area. Specifically, the study shows that:

(1) The spontaneous abortion index for the Alsea Study area where 2,4,5-T is used is significantly higher than the index for urban or rural control areas where there is little or no known use of 2,4,5-T.

(2) There is a significant increase in the abortion index in the study area relative to the control area in the months of June and July. This increase follows by approximately two months a period in March and April when 2,4,5-T is used to control vegetation in the forested areas in which these women live.

(3) Statistical analyses of these data indicate that there is a significant correlation between 2,4,5-T used in the study area during the spraying season and the subsequent increase in the spontaneous abortion index in the study.

This relationship between exposure to 2,4,5-T spraying and an increased incidence of miscarriages in humans is not surprising. This is the same relationship that has been demonstrated to exist in test animals through

*/ Although the study addressed only 2,4,5-T usage, it is now known that silvex was also used in the Alsea area during the period of the study.

numerous animal studies. While there are uncertainties concerning the amount of 2,4,5-T and/or TCDD to which the Study area women ~~were~~ (may have been) exposed and concerning the precise route (or routes) of human exposure, the statistically significant incidence of miscarriages described above makes it ~~prudent~~ reasonable for the Agency to conclude that these women in the Alsea study area were exposed to 2,4,5-T. In addition, because of the relative toxicities of 2,4,5-T and TCDD, the Agency concludes that it is reasonable to assume that any adverse reproductive effects attributable to low-level exposure to 2,4,5-T are primarily due to its contaminant, TCDD. Since silvex contains TCDD, the Agency may reasonably assume that exposure to silvex may also cause adverse reproductive effects.

Therefore, the Agency concludes that it is also ~~prudent~~ reasonable to assume that individuals may be exposed to silvex and/or TCDD who frequent or live in areas where silvex is used in ways and under conditions which may cause them to experience exposure opportunities qualitatively similar to those experienced by the Study area women. The Agency has concluded that silvex use patterns involving exposure opportunities qualitatively similar to those experienced by the Study area women are the forestry, rights-of-way, pasture, home and garden, commercial/ornamental turf and aquatic weed control/ditch bank uses of silvex. The Agency has identitfied pesticide applicators and persons involved in pesticide application support activities, and persons living

in or frequenting, areas of silvex use as the principal groups of individuals who may be exposed as a result of the forestry, rights-of-way, and pasture uses of silvex. Based upon the animal test data and other information, including the Alsea study, the Agency has concluded that individuals exposed to silvex and/or TCDD may experience adverse reproductive effects and cancer. Accordingly, the Agency concludes that it is prudent to regard individuals who may experience exposures qualitatively similar to those experienced by the Study area women as a result of the forestry, rights-of-way, pastures, home and garden, commercial/ornamental turf and aquatic weed control/ditch bank uses, as individuals who may suffer reproductive effects or cancer as a result of these uses of silvex.

B. Summary of Findings on Benefits During the Cancellation Proceedings

The suspended uses (forestry, rights-of-way, pastures, home, aquatic weed control/ditch bank, and commercial/ornamental turf) comprise about 67% of the estimated 2.8 to 3.3 million pounds of silvex used in the United States.

I find that the economic impact of either an initial 3 1/2 month emergency suspension or a 2-year suspension will be insignificant, based on several considerations. The inherent flexibility in the tratment schedules permits delays in treatment during the suspension period. Alternative chemicals, mechanical, and manual control treatments are available and are currently being used. Even though these alternatives may not generally be as cost-effective as

silvex, their availability will minimize the impacts of the suspension period. The major significance of a silvex suspension is that silvex would not be available for more extensive use on forest and pasture sites as an alternative for 2,4,5-T.

(1) Forestry

Use of silvex in forestry is primarily for release of young conifers and site preparation activities. However, silvex is not widely used because of its relatively limited control spectrum and toxicity to pines. The only extensive forestry use of silvex in recent years has been by the Bureau of Land Management in Western Oregon. (Use of 2,4,5-T and picloram was prohibited or restricted by the Interior Department in 1970).

Several chemical, mechanical (including controlled burning) and combination methods are available as alternatives for site preparation. Only silvex, 2,4,5-T and 2,4-D are preferred for the release of conifers; however, for this purpose 2,4-D has the most limited control spectrum. Manual methods are also available for release activities.

I find that the suspension of the forestry uses of silvex for a 3 1/2 month or 2-year period would not have any significant economic impact, because the principal past users, the United States Department of the Interior and Forest Service, have recently almost completely discontinued use of the

herbicide. Both agencies have already absorbed the additional costs of using alternatives.

(2) Rights-of-way

Silvex is used to control woody and herbaceous plants on railroads, highways, electric transmission lines and pipelines. Chemical, mechanical and manual methods of control are often combined for use on rights-of-way acreage, with manual and mechanical methods the most commonly used.

If silvex were not available, users would use alternative herbicides, since combinations of these provide equivalent control, and are cheaper than silvex. Therefore, I find that suspension of silvex use for 3 1/2 months or two years on rights-of-way would have no economic impact.

(3) Pasture

Silvex weed control in pastures is now practiced on only a very small proportion of the nation's pasturelands. Generally, users prefer other chemical herbicides to silvex for use in pastures. There are effective chemicals and/or mechanical control alternatives, although these alternatives may be more expensive than silvex.

If silvex were not avaiable, current users would probably adopt one of the alternative herbicides. In so doing, their incomes may be reduced by the small additional cost of using the alternative. I find that this impact of a 3 1/2 month or 2-year suspension would be nominal.

(4) Commercial/Ornamental Turf

Silvex use on ornamental turf (golf courses, parks, athletic fields, etc.) may be as high as two million pounds. Use on golf courses is extensive. Silvex is generally applied in combination with other herbicides. Use of combinations of the same herbicides, without silvex, is estimated to be as effective and comparably priced.

Without silvex, users would shift to the readily available alternatives. I find that the economic impacts on this group of users would be minimal if silvex were suspended for 3 1/2 months or two years.

(5) Home and Garden

Most homeowner use of herbicides in the United States is for control of weeds in lawns. Less than 25% of the U.S. homeowners use herbicides. As with use on commercial/ ornamental turf, silvex is usually used on lawns in combinations with other herbicides. These combinations are considered equally as effective without silvex, and comparatively priced.

If silvex were no longer available, homeowners would switch to the alternative combinations. I find that the impact of suspension for 3 1/2 months or two years would be negligible.

(6) Aquatic Weed Control/Ditch Bank

Silvex is used to control aquatic weeds in static water areas used for recreation and in farm ponds used for watering livestock. It controls submerged, emerged and

floating weeds. Essentially all weeds controlled by this use of silvex are sensitive to other aquatic herbicides or biological agents.

Silvex is also applied to drainage ditch banks and canal levees. Although there are no known chemical alternatives for control of a few of the weed pests found in these areas, there are registered chemicals which are effectve against many of them. Manual and mechanical methods are also available.

I find that the suspension of silvex for 3 1/2 months or two years would not be a significant economic burden on users for control of weeds in static bodies of water, because of the availability of effective, economical alternatives. The effect of a suspension on ditch/canal users would be somewhat greater because of the resistant weeds. Nonetheless, I find that the impact of the suspension of silvex would be nominal.

C. Summary of Findings on Imminent Hazard

(1) Forestry Use

In order to find an imminent hazard, I must find that the risks of use during the period likely to be required for cancellation proceedings appear to outweigh the benefits. The Alsea study, establishing correlation between use of 2,4,5-T in forest management and miscarriages in humans, coupled with animal studies showing similar effects, indicates that there is a substantial likelihood that serious harm could result to persons with qualitatively similar exposure

from the forestry use of 2,4,5-T. Because of the high probability that the adverse effects attributable to low levels of 2,4,5-T are primarily due to its TCDD contaminant, comparable exposure to the TCDD contaminant in silvex would result in similar risk potentials.

At this point, because of the voluntary discontinuation of the forestry uses of silvex by the major users, there appear to be no risks or benefits of its use during a cancellation proceeding. However, since forestry use of 2,4,5-T is being suspended, the real possibility of the reinstatement of silvex must be considered. In that event, I conclude that the risks of the forestry uses of silvex outweigh the benefits. The economic impacts of suspension would be small because of the flexibility of treatment schedules and the availability of alternatives. Hence, I find that an imminent hazard exists for the forestry use of silvex.

(2) The Rights-of-Way Use

The use patterns of silvex for rights-of-way use create the same, or greater, potential for human exposure as the forestry use. Hence, the rights-of-way use results in a hazard to human health which in my judgment outweighs the corresponding benefits. A use moratorium during the cancellation proceedings would not have a significant economic impact because many rights-of-way managers are

likely to use alternate chemicals which are available and, taken as a whole, are relatively similar in cost and effectiveness. Therefore, I find that an imminent hazard exists for the rights-of-way use of silvex during the cancellation proceedings.

(3) Pasture Use

The use of silvex on pastures results in a lower potential for exposure than the use of silvex in forestry because silvex is applied in pastures for spot treatment by knapsack spraying equipment. The forestry use involves substantial application by aerial methods, which have a greater potential for creating drift than does ground equipment.

The benefits of pasture use of silvex are marginal. Silvex weed control is practiced on a very small portion of pasture acreage, showing the relative unimportance of the chemical for this purpose. Moreover, there are effective chemical and/or mechanical control alternatives. Hence, it is readily apparent that the risks to human health outweigh the benefits of use during the cancellation proceeding. Accordingly, I find that the use of silvex on pastures results in an imminent hazard.

(4) Commercial/Ornamental Turf

The use of silvex on commercial and ornamental turf creates the potential for the same, or greater, exposure to humans as the forestry use, and therefore presents a compar-

able hazard to human health. Although use on commercial and ornamental turf represents the largest single use of silvex, a suspension of this use would not have a significant economic impact. Users would switch to readily available, effective, economical alternatives. Therefore, I find that an imminent hazard exists for commercial/ornamental turf uses of silvex during the cancellation proceedings.

(5) Home and Garden Use

If the forestry use of silvex creates a potential health hazard for humans, the home and garden use has an even greater hazard potential. In home application, there are the additional problems of hand application by a non-professional, unlimited application frequency and rates, and high probability of bystanders. The available alternatives to silvex for home and garden use are effective and economical. Because the potential risks from home and garden use of silvex during the course of a cancellation proceeding far outweigh any of the benefits of its use, I find that an imminent hazard exists relative to this use.

(6) Aquatic Weed Control/Ditch Bank

Silvex use for the control of aquatic weeds has the potential for human exposure equal to or greater than that likely from forestry use. In addition to the exposure possibly resulting from the actual application of the herbicide, there is the possibility of exposure from contact with the treated water. The suspension of the aquatic uses

of silvex for static bodies of water would have no significant economic impact, because of the availability of alternatives; the suspension of uses for drainage ditch banks and canal levees would result in a nominal economic impact. Nevertheless, when viewed as a whole, I find that the potential risks of these uses outweigh the benefits. Therefore, I find that an imminent hazard exists for the period of the cancellation proceeding relative to these uses.

D. Summary of Findings on Emergency

As previously discussed, I have interpreted the statutory provision on emergency suspensions [FIFRA Section 6(c)(3)] to require a preliminary balancing of risks against benefits of use during the time for holding a suspension hearing. Hence, an emergency finding involves two issues: (1) immediate intervention is required because there is not time to hold a suspension hearing before the next period of pesticide use; and (2) the risks outweigh the benefits during the time for holding the suspension hearing. At the end of the suspension proceeding, I have discretion to affirm, modify, or reverse my suspension order.

(1) Forestry Use

There is not enough time to hold a hearing before the next forest spraying season. The next spray season begins in March. I am advised that in some parts of the Pacific Northwest, spraying is about to begin or has already begun. Hence, assuming silvex use on forests poses unreason-

able adverse effects, immediate action is required to stop silvex use.

The risks posed by silvex forestry use clearly outweigh the benefits of use during the suspension proceeding which is anticipated to run from March through June (see discussion in Section V below). The Alsea study suggests that persons in the vicinity of forest spray are being exposed to TCDD-containing herbicides, and consequently suffer a potential risk from their use. Many scheduled silvex treatments can be deferred for the duration of cancellation proceedings. Therefore, those treatments can be deferred during the suspension proceedings. In any case, alternatives are often available for use in areas where treatment is deemed essential.

Accordingly, I find that an emergency exists for the forestry use of silvex. Therefore, I am ordering immediate suspension of all silvex registrations for these uses of silvex.

(2) Rights-of-Way Use

Silvex is applied on rights-of-way (railways, highways, electric transmission lines, and pipelines) during the spring growth season, which is due to start in March in some parts of the courntry. Additionally, some methods of application may be year-round. Hence, there is not enough time to hold a suspension hearing before the period of maximum use of silvex on rights-of-way.

The risk of silvex use outweighs the benefits during the time for holding the suspension proceedings. As indicated earlier, silvex poses a severe health risk to people living, working, or passing through affected rights-of-way areas; on the other hand, the benefits of use during the suspension proceedings are very small. On areas scheduled for treatment, treatment can generally be postponed for the anticipated 3 1/2 month duration of a suspension proceeding. Incremental growth during the time required to hold a suspension hearing is unlikely to be so great that treatment could not be deferred. Furthermore, there are effective and economical alternatives for the small number of instances where weed growth would interfere with equipment or endanger the safety of a system's users.

Accordingly, I find that an emergency exists for the rights-of-way use of silvex. Therefore, I am ordering an immediate suspension of all silvex registrations for the use of silvex on rights-of-way.

(3) Pasture Use

The application of silvex to restrict weed growth on pastures is expected to occur in March in some parts of the country and in even more areas before the anticipated completion of the suspension proceeding in June. Hence, emergency measures are required to prevent human exposure to silvex from pasture use during the suspension hearing.

As previously noted, the risk to humans from silvex use on pastures is roughly comparable to the risk to people in treated forest areas. On the other hand, the benefits of use during the 3- to 4-month suspension period are virtually nil. Treatment can most certainly be postponed during this short period. In any case, there are effective chemical and/or mechanical control alternatives which can be used in areas where treatment cannot be postponed.

Accordingly, I find that an emergency exists for the pasture use of silvex. Therefore, I am ordering immediate suspension of all silvex registrations for the use of silvex on pastures.

(4) Commercial/Ornamental Turf

Silvex is usually applied to commercial and ornamental turf during the spring and fall seasons. Therefore, a period of heavy usage is now pending. Moreover, in some areas of the country, use can be expected to be year-round. There is not enough time to hold a suspension hearing before the period of maximum use of silvex on commercial and ornamental turf.

The potential risks to human health from the use of silvex on commercial/oramental turf outweigh the benefits of use during the time necessary to hold a suspension proceeding. As indicated above, the use of silvex on ornamental turf during this period, would pose at least the same hazard as forestry use for a similar period. The

benefits of use during the time required for a suspension proceeding would be minimal. In most cases where treatment was necessary during this period, users would switch to alternatives which are effective and comparably priced.

Accordingly, I find that an emergency exists for the use of silvex on commercial/ornamental turf. Therefore, I am ordering an immediate suspension of all silvex registrations for the use of silvex on commercial/ornamental turf.

(5) Home and Garden

Home and garden use of silvex normally occurs in the spring and fall. However, as in commercial/ornamental turf use, application could be year-round in some areas of the country. Therefore, because of the nearness of a major usage period, and the probability of continuous use in certain sections of the country, emergency measures are necessary to prevent possible substantial human health hazards during the course of the suspension hearing.

As previously indicated, the potential threat to humans is probably greater from the home and garden use of silvex than from its forestry use. The fact that use of silvex by homeowners is almost entirely aesthetic, rather than for other purposes, indicates that the economic benefits of their use are marginal at any time. For the few areas where some control method may be necessary during the period of the suspension proceeding, effective and economical alternatives are available.

Accordingly, I find that an emergency exists for the home and garden uses of silvex. Therefore, I am ordering an immediate suspension of all silvex registrations for this purpose.

(6) Aquatic Weed Control/Ditch Bank

The application of silvex to restrict aquatic weed growth is generally begun in the spring and continued through early summer. Hence, there is insufficient time to hold a suspension hearing before humans are exposed to the potential risks to their health due to this use of silvex.

The potential human risks from the aquatic use of silvex during the suspension hearing clearly outweigh the benefits of use during that limited period. The human health hazard is at least as great as that from forestry use. The benefits to be derived from the aquatic use of silvex during a suspension hearing are very small. In most instances, the use of any herbicide could be deferred for this short period of time. However, for static water areas where some herbicidal use would be necessary, there are available chemical alternatives; for the few drainage ditch and canal levee areas which contain pests resistant to chemical alternatives, manual methods could be used.

Accordingly, I find that an emergency exists for the aquatic weed control/ditchbank use of silvex. Therefore, I am ordering an immediate suspension of all silvex registrations for these purposes.

IV. DETAILED FINDINGS CONCERNING IMMINENT HAZARD AND EMERGENCY

In Section III of this notice, I have presented a summary of my findings that an imminent hazard and emergency exist for the forestry, rights-of-way, pasture, home (and garden), aquatic weed control/ditch bank, and commercial/ornamental turf uses of silvex. The data, information, and analyses upon which these findings are based are detailed below.

A. Findings Relating to Adverse Effects in Test Animals

(1) Adverse Reproductive Effects in Test Animals

This section presents the test animal data upon which I relied in finding that exposure to TCDD and/or silvex is likely to result in adverse reproductive effects in humans. Except as specified below, these data were derived from studies in which pregnant rodents or primates were orally exposed to the test substance during the second trimester of the gestational period. The pregnant rodents were sacrificed shortly before parturition, and live fetuses were examined for abnormalities. The Agency has extracted key data for presentation in this report of findings. Experimental details and descriptions of the underlying data are available in the 2,4,5-T RPAR notice and in the published literature.

(a) Exposure of Test Animals to TCDD

TCDD produces fetotoxic effects such as death and reduced fetal size; skeletal deformities such as cleft palate and clubfoot; injury to internal organs such as intestinal bleeding, intestinal lesions, and abnormal kidneys; and post-partum effects such as reduced survival. These effects appear in several different rodent strains and species, occur in all of the litters in some dose groups, and occur at doses (at least) as low as 0.01 ug TCDD/kg. The repeated and regular appearance of several different forms of damage to test animals of several different strains and species indicates that TCDD is a teratogenic and fetotoxic agent in mammals.

(i) Fetotoxic and Embryolethal Effects

Fetotoxic and embryolethal effects have been reported for at least three different mouse strains, two different rat strains, and one strain of subhuman primates exposed to TCDD during gestation. For example, in studies using generally low-dose regimens of TCDD, Neubert and Dillmann reported that resorption sites (resorbed or dead embryos) occurred in 54% (7/13) of the litters at 0.3 ug/kg and in 100% (3/3) of the litters at 9.0 ug/kg for NMRI mice, compared to 24-32% (23/95 and 24/65) of litters exhibiting resorptions in control animals which had not been exposed to TCDD. Sparschu et al. reported resorption of 100% (110/110) of the fetuses in Sprague-Dawley rats exposed to 8 ug

TCDD/kg, compared to 20% resorption (63/309) of the fetuses from the control animals. Khera and Ruddick reported 100% (77/77) resorption of fetuses at 4 ug/kg and 36% (56/153) at exposures of 1 ug/kg in Wistar rats, compared to 2-7% (3/152 and 10/127) in the control animals. Smith et al. reported resorptions in 95% (18/19) of the litters of CF-1 mice exposed to 1.0 ug/kg, compared to 74% (25/34) in the control animals; despite the high control incidence of resorptions in this study, the increased incidence in the experimental animals was statistically significant. In an abstract of a current study, Schantz et al. (1979) reported 57% (4/7) of pregnant monkeys aborted and one delivered a stillbirth. Two others on the 50-ppt diet failed to conceive, and two delivered normally. The eight control animals all delivered normal infants. Maternal toxicity was observed in some dose groups in some of these studies.

Similar effects have been reported at higher dose levels of TCDD. Neubert and Dillmann reported that a single dose of 45 ug/kg to NMRI mice on day 6 produced resorptions in 100% (3/3) of the viable litters, compared to resorptions in 24% (23/95) of the control litters. Courtney reported an average of 87% mortality in 6 litters of CD-1 mice orally exposed to 200 ug/kg, compared to an average mortality of 6% in 15 vehicle control litters. This investigator also reported an average of 76% mortality in 6 litters of CD-1 mice exposed subcutaneously to 200 ug TCDD, compared to 14%

in the six litters of control animals. Some of these studies also describe statistically significant weight depression in the surviving embryos (e.g., Sparschu et al.).

These and other studies also report that TCDD had no measureable adverse effects at some dose levels in some strains. For example, Khera and Ruddick report no fetotoxic effects at 0.125 ug/kg in Wistar rats, and Neubert and Dillmann report no teratogenic effects at 0.3 ug/kg in NMRI mice. Courtney and Moore reported that TCDD had no effect on fetal weight or embryonic mortality at 0.5 ug/kg in CD rats, and Sparschu et al. reported no effect at 0.03 ug/kg in Sprague-Dawley rats.

Dow Chemical Company, a silvex registrant, has recently completed a study of the effects of TCDD on reproduction in Sprague-Dawley rats exposed to low dose levels of this chemical for three generations. The registrant concluded that "impairment of reproduction was clearly evident among rats ingesting 0.01 or 0.1 ug TCDD/kg/day. Significant decreases were observed in fertility, litter size, gestation survival, post-natal survival and postnatal body weight." In addition, exposure to 0.001 ug TCDD/kg per day resulted in statistically significant increases in

per day resulted in statistically significant increases in the percentage of pups dead at birth and/or dying before the end of three weeks of life in some generations.*/

Although the experimental protocols and strains differ for the several studies cited, in each case TCDD significantly increased the incidence of resorbed (or stillborn animals) embryos relative to the rate observed in control animals not exposed to TCDD. The regular occurrence of embryonic death in studies by different investigators in primates and in different rodent strains indicates that exposure to TCDD during mammalian gestation may result in the death of the embryos and related maternal reproductive failure.

(ii) Skeletal Anomalies

Skeletal defects appear in six studies involving four different mouse strains. Courtney and Moore report the following incidences of cleft palate in the indicated

*/ Dow Chemical Company has claimed that the results of this study are "trade secret" or "confidential." An injunction issued on April 4, 1978, in the case of Dow Chemical Co. v. Costle, Civil Action No. 76-10087, U.S. District Court for the Eastern District of Michigan (Northern Division), arguably precludes EPA from disclosing the data from this study at the present time. Although the relevant provisions of FIFRA have since been amended to allow disclosure of data such as this [see, e.g., FIFRA Section 10(d) and 10(g)], the injunction has not yet been modified. EPA intends to promptly request the Court to modify the injunction, but until this has been done the Agency will not publicly disclose the data from the study. The summary presented in the text of this Order does not, in EPA's opinion, constitute disclosure of the allegedly "trade secret" data submitted by Dow and would not cause any harm to Dow's legitimate competitive interests. The data from the study may be made available to any party in a suspension or cancellation proceeding under an appropriate protective arrangement.

strains exposed to 3 ug/kg TCDD: 71% (5/7) in litters of C57BL/6 mice, compared to none (0/23) in the controls; 22% (2/9) in litters of DBA/2 mice compared to none (0/23) in the controls; and 30% (3/10) for CD-1 mice, compared to none (0/9) in the controls. Neubert and Dillmann, also using 3 ug TCDD/kg, reported 29% (7/24) of the viable litters had fetuses with cleft palate for NMRI mice compared to 6% (10/160) of the control litters. Smith et al. reported cleft palate in 71% (10/14) of CF-1 mouse litters at 3 ug/kg, compared to none (0/34) in the controls.

In exposures of shorter duration, Moore et al. reported cleft palate in 86% (12/14) of C57BL/6 mouse litters exposed on days 10-13 to 3 ug/kg, compared to none (0/27) in the control litters. Neubert and Dillmann reported cleft palate in 71% (10/14) of litters of NMRI mice exposed to a single 45 ug/kg dose on day 11, compared to 6% (6/95) of litters in the controls.

Courtney and Moore reported no cleft palate in any of the litters in CD rats exposed to 0.5 ug/kg. Similarly, Khera and Ruddick, using Wistar rats, reported that the occurrence of the skeletal anomalies in the fetuses exposed to 2.0 ug/kg was comparable to the rate for the untreated animals.

(iii) Injury to Internal Organs

Exposure to TCDD produced injury to the kidneys and intestinal tracts of at least five different mouse and rat

strains. Smith et al. reported 28% (4/14) of litters with kidney anomalies at 3 ug/kg in CF-1 mice, compared to none (0/34) in the controls. Moore et al. reported 100% (14/14) of litters with kidney anomalies in C57BL/6 mice exposed to 3 ug/kg on days 10-13, compared to none (0/27) in the control litters. Courtney and Moore reported kidney anomalies in 100% (10/10) of the litters of CD-1 mice at 3 ug/kg, compared to 33% (3/9) in the controls, and 67% (4/6) litters with abnormal kidneys in the CD rat at 0.5 ug/kg as compared to none (0/9) in the control litters. Sparschu et al. reported hemorrhages or lesions in the intestine of 36% (36/99) of the fetuses of Sprague-Dawley rats exposed to 0.5 ug/kg, compared to none (0/246) in the control fetuses.

(b) Exposure of Test Animals to Silvex

Silvex has been shown to produce fetotoxic effects such as fetal mortality, reduced body weight, skeletal anomalies, and injury to internal organs. The effects have been observed in test rodent species at maternal doses as low as 50 mg/kg (TCDD < 0.05 ppm). These results clearly indicate that silvex is fetotoxic and teratogenic in mammals.

Courtney*/ reported significant incidences of increased fetal mortality and reduced fetal weight in CD-1

*/ Courtney, K.D. 1977. Prenatal effects of herbicides: evaluation by the prenatal development index. Arch. Environ. Contam. Toxicol. 6(1):33-46.

mice which had received prenatal exposure to silvex. Maternal subcutaneous exposure to 405 mg/kg silvex (TCDD < 0.1 ppm) resulted in 25% (33/132) fetal mortality and an average fetal weight of 0.87 g, compared with control values of 12% (19/171) and 1.03 g, respectively. Oral exposure to the same dose resulted in an average fetal weight of 0.83 g, compared with 1.01 g in the controls. An increased incidence of cleft palate was also observed among the treated fetuses. Oral exposure resulted in an incidence of 7% (7/95); subcutaneous exposure resulted in 3% (3/99). No cleft palates (0/260) were observed among the control animals.

Dow Chemical Company*/ studied the reproductive effects of silvex and the propylene glycol butyl ether ester of silvex (silvex-PGBE), each containing less than 0.05 ppm TCDD. Sprague-Dawley rats were exposed to 25 to 100 mg/kg on days 6 through 15 of gestation. Significant effects on fetal mortality and birth weight were observed in the litters of treated dams. Skeletal anomalies, such as cleft palate, retarded ossification, and extra cervical ribs were observed among the exposed fetuses. Micropthalmia (abnormal smallness of the eyeball) and circulatory system abnormalities were also seen. Similar effects were observed when animals were dosed with silvex-PGBE, or when dosed for three-day intervals during the period of early organogenesis.

*/ Dow Chemical Co. has also requested confidentiality for the results of this study. The discussion in the footnote in Section IV.A.(1)(a)(i) of this document applies to these data.

In each of the studies cited above, some maternal toxic effects were observed. Courtney found increased maternal weight gains and increases in liver to body weight ratios among the treated groups; Dow noted baldness (alopecia), lack of appetite and vaginal bleeding. However, the existence of maternal toxic effects does not negate the impact of the observed injury to and death of the fetus.

(2) Oncogenic Effects in Test Animals: Exposure of Test Animals to TCDD

The Carcinogen Assessment Group (CAG) has concluded that TCDD induces carcinogenic responses in mice and rats at exceedingly low dose levels and that these effects, together with data showing that TCDD is mutagenic, constitute substantial evidence that TCDD is likely to be a human carcinogen.

Dow Chemical Company, a silvex registrant, studied the effects of TCDD on male and female Sprague-Dawley rats exposed to 0.022, 0.220, or 2.2 ppb TCDD. CAG agrees with the registrant's conclusion that there is a statistically significant increase in the incidence of heapatocellular carcinoma in female rats exposed to 2.2 ppb TCDD. In another study using Sprague-Dawley rats, Van Miller reported that 1 ppb and 5 ppb TCDD produced a carcinogenic response in the livers of male Sprague-Dawley rats. These observations tend to confirm the registrant's observations that TCDD produces an oncogenic response in the livers

of male Sprague-Dawley rats.**/ Further, a preliminary report of a not-yet-completed National Cancer Institute study tends to confirm these observations of a carcinogenic response in rats. A contractor for the National Cancer Institute has reported that TCDD is carcinogenic in the rats and mice used in that study.

CAG also emphasized that, at low levels, TCDD is a potent inducer of arylhydrocarbon hydroxylase, an enzyme system that contains an enzyme that is known to mediate the formation of epoxides, compounds which are potentially active carcinogenic metabolites.

CAG also reported that TCDD is mutagenic in the Ames test without the metabolic activation system. Its mutagenic activity is exhibited by frameshift mutations caused by intercalation between base-pairs of DNA.

B. Findings Relating to Risk to Humans

(1) Study of Miscarriages in Alsea, Oregon

The Alsea study detailed below was performed taking into consideration only 2,4,5-T applications during the reference period. Information has recently become available to the Agency which documents the use of silvex in the

**/ The CAG and an EPA audit found that this study had major shortcomings in design and conduct that limited the reliability of the data developed at dose levels lower than 1 ppb.

Alsea area during the period of time studied.*/ However, even without this information, I would have found that the serious implications of this study are as applicable to silvex as to 2,4,5-T. TCDD, the contaminant contained in both herbicides, is a potent mammalian fetotoxin and teratogen at very low doses. Conversely, silvex and 2,4,5-T are fetotoxic and teratogenic at comparatively high doses. It is reasonable to assume that the adverse human reproductive effects observed in Alsea which have been attributed to low-level exposure to 2,4,5-T are due primarily to the TCDD in the 2,4,5-T. Therefore, since silvex also contains TCDD, I conclude that the Alsea data are applicable to areas where silvex is used when evaluating potential reproductive risk to humans.

(a) General Discussion

In response to the 2,4,5-T RPAR notice, a group of eight women informed the Agency that they lived within 12 miles of Alsea, Oregon, where 2,4,5-T and silvex are used in forest management and that they had experienced a total of 13 miscarriages between 1972 to 1977. In their letter, the women presented information showing that most of their

*/ Herbicide spray records for Alsea basin, 1972-1978 (EPA 1979). Use of silvex was also claimed by the women in the 2,4,5-T RPAR response which prompted the Alsea study [2,4,5-T RPAR rebuttal comment, 30000/26:#363].

miscarriages occurred eight to ten weeks after conception and followed by four or six weeks the date of the spring application of 2,4,5-T in the forest areas in which these women reside. The women indicated their belief that this information suggested that the unusually high number of miscarriages in their group was related to the use of 2,4,5-T and/or silvex.

The effects which these women reported were comparable to the embryolethal and fetotoxic effects observed in test animals that have been exposed to 2,4,5-T and/or TCDD. Moreover, because embryos are particularly susceptible to the harmful or lethal effects of fetotoxic or teratogenic agents during the early stages of pregnancy, the occurrence of these miscarriages within approximately two months of the use of 2,4,5-T in the Alsea area suggested a possible relationship between the use of the pesticide and the miscarriages reported for this group of women. For these reasons, the Agency began an epidemiological study to determine if the occurrence of the spontaneous abortions in the entire Alsea area (parts of three counties comprising 1,600 square miles) bore any relation to the use of 2,4,5-T in the area. To answer this question, the Agency gathered information and data from hospitals on the occurrence of spontaneous abortions in the Alsea Study area and compared these data to comparable data from a rural area where there was little or no known use of 2,4,5-T or other dioxin-contaminated

phenoxy herbicides (Control area). Data on spontaneous abortions from an Urban area near Alsea were also reviewed for the study.

The Agency's preliminary analysis of the data generated through this study indicates that:

(1) The spontaneous abortion index*/ (hospitalized miscarriages per 1,000 births) for the Alsea Study area where 2,4,5-T was used was significantly greater than the index for the Urban and Control areas where there was little or no known use of 2,4,5-T;

(2) There was a dramatic increase in the spontaneous abortion index for the Study area relative to the Urban and Control areas in the months of June and July; this increase followed, by approximately two months, a period in March and April when 2,4,5-T was used to control vegetation in the forested Study area; and

(3) Statistical analyses of these data indicated that there was a significant correlation between the amounts of 2,4,5-T used in the Study area during the spraying season and the subsequent increase in the spontaneous abortion index in the Study area.

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*/ The investigators determined the spontaneous abortion index by relating the number of hospitalized spontaneous abortions to the number of live births, corresponding to month of conception. The ratio derived in this way is express as abortions/1,000 births, related to month of conception, and permits comaprison between areas of different total population size. The index is based on a five-month moving average for births to correspond with monthly miscarriages for terms up to 20 weeks (about five months).

In conclusion, the Agency's systematic survey of the occurrence of spontaneous abortions in an area of 2,4,5-T use indicates that there was an unusually high number of spontaneous abortions in the area, and that the incidence of spontaneous abortions may reasonably be related to the use of 2,4,5-T in the area. The data further indicate that the miscarriage experiences which the eight Alsea women reported to the Agency were representative of the experiences of the larger population of women living in the Study area. The data and information which provide the basis for these conclusions are summarized below.

(b) Results and Analysis

Comparison of the spontaneous abortion indices for the Study, Urban, and Control areas for the period from 1972 through 1977 shows that women living in the Study area where 2,4,5-T is used were more likely to experience spontaneous abortions than women living in either the Urban or Control areas (Table 1). The six-year spontaneous abortion index averaged 80.8 for the Study area, compared to averages of 43.8 and 65.4 for the Urban and Control areas, respectively.

In addition to this general elevation in the Study area spontaneous abortion index, there was a striking increase in the Study area index for the months of June and July. During June, the index in the Study area was 130.4, compared to 44.9 and 46.0 in the Urban and Control areas, respectively.

Table 1. Monthly Spontaneous Abortion Index for the Study, Urban, and Control Areas (Oregon, 1972-1977)

Month	Study Area	Urban Area	Control Area	Average
January	48.1	73.9	82.0	68.0
February	82.2	49.3	28.1	53.2
March	93.8	43.9	48.1	61.9
April	61.9	47.0	97.5	68.8
May	89.9	50.8	63.2	68.0
June	130.4	44.9	46.0	73.8
July	105.4	14.6	55.3	58.4
August	88.1	31.8	79.8	66.6
September	46.0	49.6	85.3	60.3
October	76.2	54.8	50.5	60.5
November	76.7	19.6	54.3	50.2
December	70.3	45.6	94.5	70.1
Average	80.8	43.8	65.4	63.3

For July, the indices were 105.4 for the Study area, compared to 14.6 and 55.3 for the Urban and Control areas, respectively. These data are presented graphically in Figure A.

The increased spontaneous abortion indices in the Study area during June and July are particularly significant when viewed in terms of data on the use of 2,4,5-T in the Study area.*/ Spraying records for the Alsea area for the

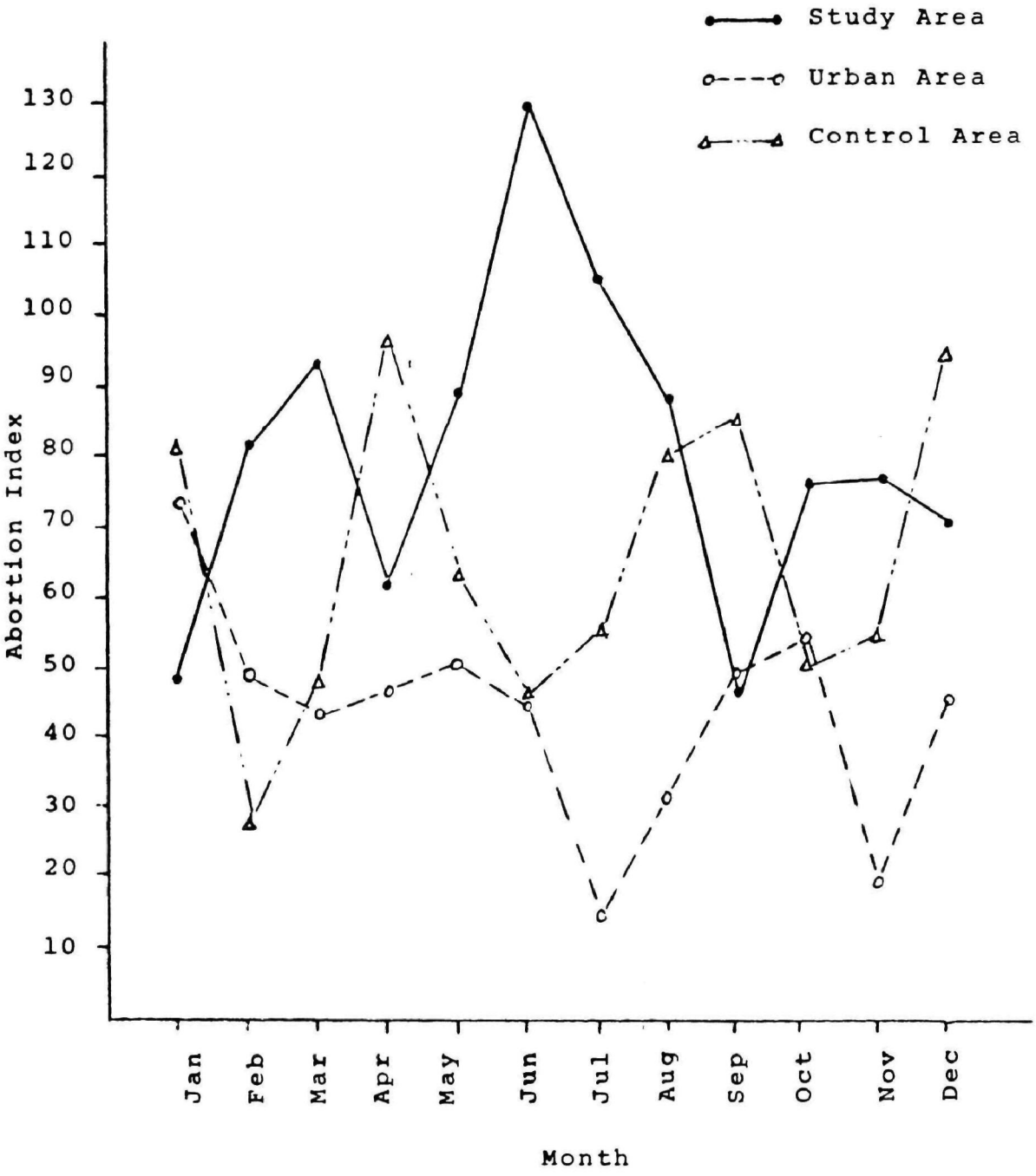
*/ The preliminary report inadvertently included 3,530 pounds of silvex as 2,4,5-T in the estimates of usage in the Study area. Conceptually, this flaw is not significant: 1) since its effect would merely modify slightly the very significant correlation coefficient between herbicide use and miscarriages; 2) the nature of the relationship between time of application and the miscarriages is expected to remain unchanged; and silvex contains TCDD and could be expected to result in the same effect.

Nonetheless, the Agency immediately had the analysis rerun to determine whether specific change in numerical estimates result.

Corrected 2,4,5-T use remained significantly correlated with miscarriages occurring 2-3 months later ($r=72$; $p<.01$). Combined silvex and 2,4,5-T spray data were also correlated with miscarriages since both compounds could be hypothesized to cause the observed effect due to a common TCDD contaminant. This analysis also showed strong correlation between use and miscarriages as would be expected on the basis of animal studies ($r=.69$; $p<.02$).

The relative insensitivity of the correlation to changes in quantity further demonstrates the inherent strength of the relationship between the basic use pattern and miscarriages occurring 2 to 3 months later.

Figure A. Plot of Monthly Spontaneous Abortion Index for the Study, Urban, and Control Areas

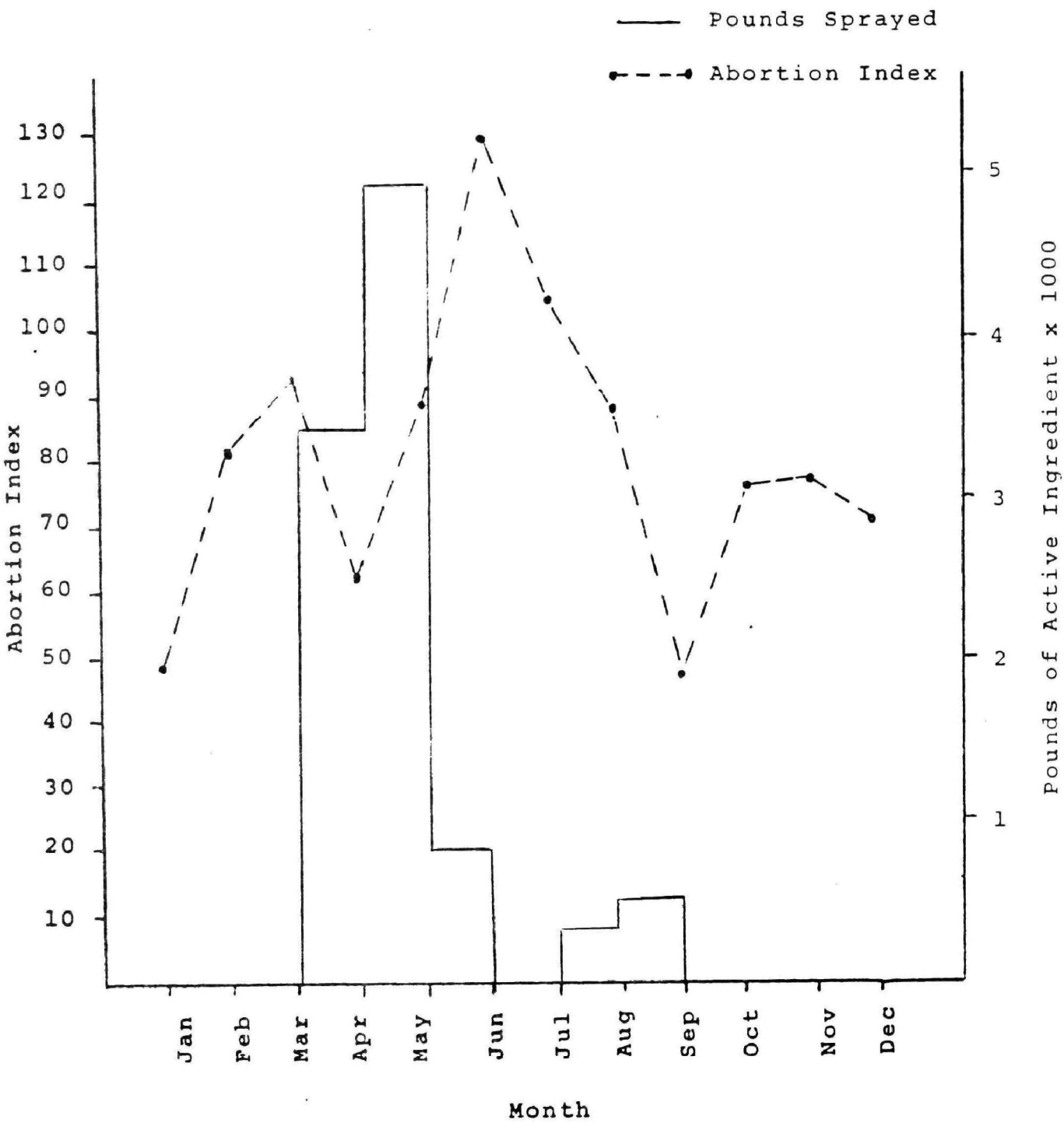


study period indicate that 2,4,5-T use occurs primarily between March 1 and April 30; substantially lower amounts of the pesticide are used during May and still lower amounts are used during July and August (Figure B). Examination of this information on the use of 2,4,5-T in light of data on the increased incidence of spontaneous abortions reveals that this increase occurs approximately two months after the period of annual application of 2,4,5-T in the Alsea area.

More refined analysis of these data on total abortions and total 2,4,5-T use by month during the period from 1972 to 1977 indicates that there was a statistically significant correlation between the abortion index in the Study area and the amount of 2,4,5-T used there. That is, when the increased spontaneous abortion index was compared to the amount of 2,4,5-T used each month in the areas where the women resided, the peak in the abortion index followed the peak in the spray pattern by approximately two months. This two-month lag time corresponds to the time predicted on the basis of the initial reports from the eight Alsea women. Because this correlation is statistically significant ($p<0.01$), there is strong reason to suspect that the spontaneous abortion increase was related to the use of 2,4,5-T.

In view of the laboratory data establishing that 2,4,5-T and its contaminant TCDD have embryolethal effects in test animals and the susceptibility of the young embryo

Figure B. Pounds of 2,4,5-T Sprayed in Alsea Basin Accumulated by Respective Month, 1972 through 1977, Compared with Abortion Index for the Same Period



to fetotoxic and teratogenic agents, the increased spontaneous abortion index in an area of 2,4,5-T use may reasonably be interpreted to be a consequence of the exposure of women residents of the area to the 2,4,5-T used for forest management.*/

(2) Seveso (Italy) and Vietnam

(a) Seveso, Italy

On July 10, 1976, an accident at the ICMESA chemical plant in the Seveso region of Italy released 2 to 10 pounds of TCDD over a wide area. Hundreds of animals died, many area residents reported skin disorders, and an area of 110 hectares was evacuated. The most pertinent reports on this incident are provided by Reggiani (1977), Tuchman-Duplessis (1977), and Whiteside (1977; 1978).

There is an apparent consensus that the reproductive epidemiology of Seveso, as presented, does not provide firm evidence of increased risk of spontaneous abortions or congenital malformations following the explosion. The Agency does not believe, however, that those investigations

*/ The Alsea experience may not be an isolated incident. Reports of people adversely affected by exposure to phenoxy herbicides and/or TCDD have frequently appeared in medical and scientific journals. Recent summaries appear in IARC, NRCC, and U.S. Air Force documents on phenoxy herbicides and dioxins. Further, as a result of the 2,4,5-T RPAR, the Agency recently received numerous accounts of human health effects attributed to phenoxy herbicides and/or TCDD. These have been summarized in a document included in the record. The cumulative effect of these reported incidents suggests that people who live and/or work in areas of 2,4,5-T use may experience adverse health effects.

provide sufficient evidence of the absence of increased teratogenic risk in humans, either for dioxin in general or among the women of Seveso in particular. There are three reasons for this conclusion: (1) deficiencies in the available data; (2) methodologic deficiencies in the treatment and interpretation of the data which are available; and (3) suggestive indications in the available data that there may actually have been an increase in teratogenic risk in the area after the incident.

Major points which illustrate deficiencies in the available data include: reproductive data in the area "either do not exist or are deliberately underreported" (Reggiani 1977); baseline rates for spontaneous abortions and congenital malformations in the area prior to the incident are not available; less than complete cooperation was obtained from local physcians and less than complete registration of pregnant women was attained (623 pregnant women were registered, but 2,513 deliveries were recorded in the area for July 1976 to May 1977; registration was thus about 25%); while 34 women obtained therapeutic abortions in the area, it is estimated that more than 2 times that number obtained them legally or illegally elsewhere (Whiteside estimates the number to be 4 times as many); and the conventional pitfalls of reproductive epidemiology could not be avoided (e.g., dependence on hospitalized spontaneous abortions for numerators and hospitalized births for

denominators, and different gestational cohorts for spontaneous abortions and births occurring in the same calendar period).

Major points which illustrate methodologic deficiencies in the treatment and interpretation of the available data include: estimates of the total amount of dioxin released ranged from 650 g (Reggiani 1977) to 11 kg (Whiteside), to 130 kg (Nature 11/28/76); estimates of exposure per person varied from 29 ug/m^2 (Tuchman-Duplessis) to 5,620 ug/m^2 (Reggiani 1977); exposure was characterized by geographic zones, but reproductive data were gathered by geographic districts raising questions whether the zones were contiguous with the districts; spontaneous abortion rates were grouped in 6-month intervals, but congenital malformation rates for 1976 were grouped in 12-month intervals which could have masked an effect expected to be relatively acute or with a 2-3 month lag period; and the rates listed as "totals" for the two groups of districts in Table 13 (in Reggiani 1977) appear to be averages of the district rates and as such are invalid and cannot be interpreted; the lack of chromosomal abnormalities in the products of therapeutic abortions is overemphasized since dioxin could conceivably produce a teratogenic effect without producing a concomitant mutagenic effect; and the wide interspecies variation seen in lethality studies should not automatically be applied to teratogenic effects because it is known that very low doses are teratogenic in the rat (e.g., 0.01 ug/kg) and dioxin doses which caused

teratogenic effects in rhesus monkeys were apparently as low as 2.5, 50, and 500 nanograms/kg.

Suggestive indications of a possible teratogenic effect in humans, from the available data, include: the congenital malformation rate increased by 570% (about 7-fold) between 1976 and the first five months of 1977 (Table 14, 0.13 to 0.87 per 100 live births) (in Reggiani 1977). The birth rate dropped "sharply" following the explosion (Whiteside) and cows aborted and produced malformed offspring following the explosion. This lowered fertility could be evidence of increased teratogenic risk; a local doctor noted a "marked increase" in convulsions among infants. (convulsions could be delayed effects of neurotoxicity in utero).

(b) Vietnam

A large amount of TCDD-contaminated herbicides were used in Vietnam during 1962-1971. Possible health effects have been reported upon retrospectively by groups entering Vietnam. Tung et al. charged that 2,4,5-T was responsible for much of the Down's Syndrome seen in [South] Vietnam. Crummer was quoted by Honoroff as having observed high incidences of children with Down's Syndrome. Tung et al. also noted a very significant increase in the Hanoi hospitals in hepatic carcinomas in the period 1962-1968 [1790/7911 cancer cases (10%), compared to 159/5492 (2.9%) for the period 1955-1961].

It should be remembered that most of the accidents reported here were retrospective accounts. In the cases of Seveso and Vietnam, reporting was (and still is) at best piecemeal. The exposed populations contained numbers of highly mobile persons who could not be accounted for adequately.

(3) Exposure Analysis

(a) General Considerations

There are two components to any pesticide-related risk: (1) the toxicological properties of a chemical, and (2) exposure to the chemical. The risk assessment is a summation of the conclusions in each of these areas. A highly toxic chemical may pose high risk even if exposure is low; conversely, a compound of low to moderate toxicity may pose high risks if exposure is high.

Estimating probable exposure is difficult for a number of reasons. While it would be inappropriate to attempt a definitive discussion of these problems here, it is useful to note a few examples. First, empirical data on exposure is less available than is toxicology data. Second, there are a number of exposure pathways which require consideration (e.g., inhalation, dermal absorption, ingestion of food residues, and ingestion of water residues). Third, the inherent complexities of the dynamics of a chemical's movement through the environment create formidable obstacles to describing any given exposure pathway. For

example, the chemical may behave differently in various media depending upon a number of environmental factors which can vary at any one application site. Thus, even when some empirical data on a given route of exposure is available, there are often uncertainties concerning the applicability of the data to situations involving conditions which vary from those which obtained at the study site.

The inherent difficulties of exposure assessment always create a troublesome problem for decision makers. These problems are of great concern in situations involving chemicals which appear to pose risks even at very low levels of exposure. As discussed above, the TCDD contaminant in 2,4,5-T and silvex is clearly such a chemical. For example, TCDD is carcinogenic in rats at doses as low as 1 ppb and fetotoxic in mice at doses as low as 0.01 mg/kg/day.

Moreover, the complexities of exposure assessment are also amplified in situations involving persistent chemicals. This is because the length of time a chemical persists in the environment can increase the opportunities for movement of the chemical and confound attempts to eliminate pathways as pathways of concern. Time increases the possibilities of variation in enviromental factors affecting chemical mobility.

The environmental persistence of 2,4,5-T and silvex is relatively short due to physical, chemical, and biological degradation processes. On the other hand, the contaminant

TCDD has a much longer persistence in soil and is known to bioaccumulate in fish (Matsumura and Benezet, 1973; Kearney et al., 1973).

Generally, exposure assessments involve attempts at modeling the likely exposure potential through several pathways which are identified as pathways of principal concern. The exposure assessment typically will involve attempts to describe the movement of the chemical from the site of application to persons potentially at risk, using such empirical data as are available on the presence of the chemical at various intermediate points in the critical path. Conservative assumptions based upon such things as knowledge about the behavior of similar chemicals, typical environmental conditions affecting the use site, and the like, are used to bridge inevitable gaps in the empirical data. The objective, however, is a simple one: to obtain a qualitative and (if possible) quantitative description of the likelihood that a given chemical will move from where it is applied to a given group of potentially exposed individuals.

Since 2,4,5-T first surfaced as a subject of regulatory concern, determining potential exposure has been the critical issue on the risk side of the regulatory equation. Uncertainties about exposure resulted in suspension of regulatory action in 1974, and the launching of an ambitious project to generate exposure data (the "Dioxin

Implementation Plan" or "DIP"). Primarily because of great difficulties encountered in developing analytical methodologies with sufficient sensitivity to measure the extremely low levels of TCDD which are of biological concern, the progress of the DIP has been disappointing. To date, it has yielded only fragmentary information.

In my judgment, the information which has recently come to my attention as a result of the Alsea study constitutes a dramatic and troubling new point of departure for analysis of TCDD exposure concerns. As indicated above, these data show a striking relationship between 2,4,5-T use and increased incidences of spontaneous abortions among women residing in the use area. As further developed above, this effect is an effect which one would have predicted as a likely outcome of human exposure, based upon a body of animal data of almost unprecedented conclusiveness. The Alsea study, to be sure, contained no data showing actual exposure. However, concern for the health of humans who may be exposed to TCDD, and therefore to 2,4,5-T or silvex contaminated with TCDD, is heightened because scientists have not demonstrated that there is a level of exposure that has no adverse effects in humans.*/ Thus, in the face of the highly significant relationship which the study showed, and

*/ A committe of the National Research Council of Canada recently agreed with the authors of the World Health Organization's monograph on TCDD that "for TCDD a no-effect level for man could not be established" (NRCC 1978).

the animal data, I conclude it is reasonable and in the public interest to assume that the women in Alsea study were exposed to TCDD.**/

Moreover, I also conclude that it is prudent to assume that individuals who frequent or live in areas where 2,4,5-T or silvex are used may be exposed to TCDD in ways and under conditions which may cause these individuals to be exposed in ways qualitatively similar to those experienced by the Study area women.

As developed below, I find that silvex use patterns likely to cause exposure opportunities similar to the exposure experienced by the Study area women are the forestry, rights-of-way, pasture, home and garden, commercial/ornamental turf, and aquatic weed control/ditch bank uses of silvex. The Agency has identified pesticide applicators and persons involved in pesticide application support activities, and persons living in or frequenting areas of silvex use as the principal groups of individuals who may be exposed as a result of these uses of silvex.

**/ I have found it prudent to suspend because data from the Alsea Epidemiological Study indicates that women experiencing adverse reproductive effects may have been exposed to 2,4,5-T. Information of this kind concerning a chemical's effects on human populations is rarely available. Before the Alsea Study was completed, Agency scientists developed preliminary exposure analyses for 2,4,5-T based on use information, assumptions, and modeling. Since I have information of adverse human effects correlating with the use of 2,4,5-T, I have chosen to rely on this correlation as a basis for regulatory action, rather than on exposure analyses based exclusively on use information and modeling.

(b) The Alsea Study Area

(i) Description of Area

The Alsea Study Area comprises approximately 1,600 square miles of Oregon's forested Coastal Range centered around the "Alsea basin," an area of approximately 400 square miles. It is bounded on the west by approximately 70 miles of the Pacific Coast and extends inland for distances ranging from 10 to 35 miles. The Study area includes all but the northern and southern reaches of the Suislaw National Forest. Numerous commercially owned and Bureau of Land Management forested acreages are interspersed throughout this region. Mountain elevations of approximately 1,000 feet are not uncommon; peak elevation is slightly more than 4,000 feet. The principal rivers are the Siletz, Alsa, Yaquina and the Suislaw. Eastern fringes of the area drain eastward into the Willamette Valley. Maximum runoff is reached generally during the winter months as the result of storms off the Pacific occurring usually as rain.

The Study area is predominantly rural. The four largest towns have a total population of 14,450. All other towns/villages have populations of less than 1,700. Alsea has a population of 400 (1970 census). In addition, many residences are scattered througout the forest areas. All of the nine women who were idenitified in the first phase of the investigation resided, at the time of pregnancy, in rural residences located within 12 miles of Alsea.

(ii) Use Pattern

2,4,5-T is applied to the forests in the Alsea area almost exclusively by helicopter for control of undesirable vegetation such as red alder, vine maple, salmonberry, and thimbleberry. In general, the compound is used in the spring (March, April, or May) with a second application made, if needed, in middle to late summer (July and/or August). Over the six-year study period, 10,000 pounds of 2,4,5-T was distributed over a total area of approximately 7,000 acres. The usual practice was to treat any particular site approximately once every five years. However, contiguous stands could be treated in succeeding years. The spray program spans only a few days' time, with the duration depending on the number of acres to be treated and the weather conditions.

To avoid contamination of water sources prior to 1978, the general application policy was to avoid spraying near homes and to provide for a single swath of 30 to 60 feet on each side of any major stream. In September 1978, the Oregon Forest Practices Act created guidelines which prohibited spraying within 500 feet of an inhabited residence or within 200 feet on either side of streams with fish and/or ones that are used for domestic water supplies. However, drift and runoff could contaminate surface waters.

(iii) Population Exposed to the Herbicide

Population of the Alsea Region is clustered in several small towns; there are also isolated homes and farmsteads in the forest area. Other groups which may be traversing the forests of the Alsea Region include workers engaged in forest management, incidental travelers, hikers, students, surveyors, and delivery persons.

(iv) Modes of Exposure

The major method of dispensing 2,4,5-T in the Alsea Forest Region is by helicopters. Although the Oregon Forest Practices Act prohibits spraying near homes or streams, there appears a likelihood that residents and travelers of the Alsea Region might be directly exposed to 2,4,5-T during periods of application as a result of drift. Drift from a helicopter flying over a forest canopy can produce drift of the herbicidal spray at significant distances from the path of the aircraft. Residents or travelers in the path of the spray might be doused with the pesticide spray.

Exposure to the population from drift and direct contact is by the dermal (exposed skin) and inhalation routes. Resident populations may also incur exposure to 2,4,5-T and TCDD subsequent to application. Waterborne residues are a possible route of exposure; other possible

exposure routes include fish, wildlife, and other foods produced or found in the area. The fact that TCDD is somewhat persistent and bioaccumulative may enhance exposure possibilities. Furthermore, pesticide mixers, loaders, applicators, and other workers may be exposed to the pesticide.

(c) Comparison Between Presumed Exposure in The Alsea Study Area and Possible Exposure in Other Use Situations

The Alsea Study shows a significant correlation between the use of 2,4,5-T in the Alsea area and increased incidence of spontaneous abortions within approximately two months after application. The Agency believes that it is prudent to assume that the women studied were exposed to 2,4,5-T. While the Agency cannot determine the actual routes of exposure, information about how 2,4,5-T is applied, population densities, and proximity of Study area residents to spray areas provides a basis for making assumptions about possible chances for exposure.

That 2,4,5-T was applied by helicopter rather than by ground application methods in Alsea, enhanced the potential for exposure to 2,4,5-T from drift. Aerial application is a principal method for applying 2,4,5-T and silvex. Most of the phenoxy herbicides applied in forests and on rights-of-way are applied aerially. In contrast, in pastures, application of 2,4,5-T and silvex usually is by spot treatment with knapsack spraying equipment. This method, causing less spray distribution than aerial application, lessens potential exposure from drift.

Alsea inhabitants live in towns and residences scattered throughout forests in which 2,4,5-T was applied. Effects occurred even though application near residences and streams was prohibited. The Study area women who experienced spontaneous abortions were residents of the area. Their exposure to 2,4,5-T or TCDD may have occurred either while they were at home or while they were in nearby forest areas. Bystanders, workers engaged in forest management, people visiting the forests for recreational purposes, and

others would have exposure potential similar to the exposure potential of the Study area women away from their homes. Because TCDD persists in the environment, such non-residents may have been exposed to 2,4,5-T and TCDD during or for some unknown length of time after application had occurred.

The Study area women may have been exposed to 2,4,5-T or TCDD through ingestion of drinking water, fish, and wildlife. Residents are more likely to be exposed through this route than infrequent visitors to the spray area. Frequent visitors or workers in the area would have exposure potential similar to that of residents. All other forest areas in which 2,4,5-T or silvex is used are most obviously similar to the Study area.*/

The use of silvex to maintain rights-of-way involves exposure potential similar to the exposure potential of the Study area women: residents of the application area and workers and visitors who frequent the area may be exposed.

The Agency estimates that a considerable number of people may be exposed to silvex and TCDD as a result of the use of silvex in non-urban areas to maintain rights-of-way. Rights-of-way uses include highways, railway lines, electric power lines, and pipelines. A principal method of applying

*/ Commercial forests are defined as those lands not withdrawn for non-timber purposes which are capable of growing 20 cubic feet of wood per year of desirable species.

silvex is by aircraft, which was the method of application in the Alsea, Oregon area.

The population that is most likely to be exposed are people who live in the path of the spray or in the area of drift.*/ A large potential exposure group would be comprised of people living along railroad tracks and along highways. Other groups that may be exposed are those that live in forests or plains along power lines and pipelines. The residents may be exposed to TCDD through the diet for longer periods of time due to low levels of TCDD contamination in water and food. An additional potentially exposed group are people working in, or traveling through, the treated area.

Exposure from the use of silvex in pastures is likely to be lower than the Study area.**/ Pastures

*/ Factors which affect drift include wind direction and velocity, turbulence, relative humidity and air temperature, atmospheric stability, pesticide formulation, application equipment, and spray volume. For purposes of this analysis, the Agency conservatively estimated possible pesticide drift at 1/2 mile. The Agency notes, however, that pesticides could drift farther depending on the variables listed above. Some pesticide drift has been reported as far as 22 miles from target (EPA DRAFT: "Report to Congress/Study - ULV," p. 95). In addition, this same draft report estimates that percent of pesticide drift over 1,000 feet from the target variously ranges from a low of 10% to a high of 90%.

**/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

are likely to be near farmhouses and small towns. The populations which may be exposed to silvex include farm families, other rural residents, and workers in rural occupations. The predominant method of application for controlling brush in pastures is spot treatment with knapsack spraying equipment. The distribution of silvex from this technique is lower than that from forestry and rights-of-way use, because this technique produces only short-range drift. Indirect exposure due to residues in food is possible.

Generally, persons involved in applying pesticides have greater exposure to the chemicals than do residents of the area in which the pesticides are used. There is no reason to believe that this would not be true of silvex. Therefore, the Agency is concerned about potential exposure to pilots, ground spray crews, mixers and loaders, and flaggers, all of whom are exposed to silvex in the application process.*/

For aerial application, the ground crew, including mixers and loaders of the aircraft, is the group with the highest potential for exposure by both dermal and inhalation

*/ In response to the 2,4,5-T RPAR, the American Paper Institute and the National Forest Products Association recently submitted a detailed study of applicator exposure to 2,4,5-T during both aerial and ground applications (2,4,5-T RPAR submission #1023H - 30000/26). The results of this study indicate that workers who handled the pesticide concentrate had the highest exposure, followed by knapsack sprayer applicators, mist blower drivers, helicopter pilots, supervisors, and flagmen.

routes, because they handle the concentrated formulations. The flaggers on the ground are exposed mainly by drift of the diluted spray deposited on their exposed skin, and to a lesser degree by inhalation. The pilots are expected to be exposed to smaller amounts of silvex by dermal and inhalation routes because they sit in the enclosed cabin of the helicopter while applying the diluted herbicide spray. For the ground application techniques, the applicators and mixers are the workers running exposure risk. Inhalation exposure may be more significant when fine mist sprayers (for example, foliar treatment are used) in contrast to stump treatment spraying with a coarse spray. The reason for this is that smaller spray droplets are more readily absorbed through the lungs.

The exposure to silvex of persons using the pesticide for home and garden use may be higher than the exposure of most other groups potentially exposed. The exposure from home and garden use would appear to be greater than the exposure from forestry use in areas such as Alsea. Furthermore, home and garden exposure to owners/applicators may be greater than the exposure of persons involved in commercial application of silvex or 2,4,5-T since home users are not likely to wear appropriate protective clothing or to take adequate precautionary measures.

Several home and garden application techniques have inherent exposure potential. Hose-end diluters probably have a high potential for dermal exposure to both applicators and bystanders because of the long range of the spray arising from these devices. The coarseness of the spray, however, probably precludes any significant inhalation exposure or drift away from the site of treatment.

Another possibility for exposure from home and garden use occurs during the dilution of liquid concentrates of silvex. The concentrate may spill or splash onto the exposed skin of the user. Additional exposure to householders may occur during spraying, mixing, and cleanup of equipment. It is unfortunately true that householders may not exercise appropriate caution, and may, for example, spray upwind, thus receiving an unduly high amount of drift on face, hands, and other unprotected parts of the body. Other sources of potential applicator exposure include splashing and low-distance drift droplets from tank sprayers, aerosol containers, and dust particle drift from granular application.

Persons who are bystanders could also receive exposure to silvex by accidental splashing or drift, or low-level drift droplets and/or dust particles from granular formulations.

Some home and garden applications of silvex are made by lawn care professionals, who work much more extensively with this herbicide than would a single homeowner. These professionals, however, are likely to exercise more care

during the use of pesticide chemicals, and thus avoid spills or substantial dermal exposure.

Silvex is also used for weed control in sites such as public parks, golf courses, athletic fields, institutional lawns, and sod farms. These uses are similar to the home and garden uses described above. The most exposed group is likely to be the applicators. Another group of persons who may be exposed are bystanders, sports enthusiasts, residents of the institutions, etc. The routes of exposure for all these groups are likely to be chiefly dermal. The applicators are exposed not only by applying the herbicide, but also by mixing and diluting the concentrate. Bystanders and people who enter treated areas will incur less exposure than applicators, unless they get accidentially splashed or sprayed.

Silvex is used to control plants in waters used for recreation and in farm ponds. Thus, the general population may be exposed from this use of silvex by swimming, engaging in water skiing, drinking treated waters, or eating fish caught in waters where silvex has been applied.

The applicators involved in this use of silvex are professional or staff persons engaged by authorities responsible for maintaining clean waterways. Applicators apply the material from boats. Applicator exposure is likely to be greater if the applicator uses a mechanical sprayer than if the applicator pours the formulation

directly onto the water, unless spillage results accidentally from pouring. The fine mist dispensed by the mechanical sprayer could be deposited on unprotected skin or could be inhaled.

C. Determination of Benefits

The Agency has evaluated the economic effects of suspension of non-crop uses of silvex for a period of two years until completion of the decision whether these uses should be cancelled*/. The co nsideration of economic impacts stemming from a suspension is limited to a two-year period because the maximum projected length of a cancellatin proceeding would be tgwo years. A suspension order remains in effect only during a cancellation proceeding. Thus, only the impacts which would arise during this period would be at issue in a suspension. Any impacts which would be caused by a suspension, but which would be felt after this period, are also considered**/.

*/ The emergency suspension order will take effect immediately upon issuance of this Notice and remain in effect during any subsequent emergency suspension hearings. At the conclusion of the hearings, a decision will be made whether to continue or remove the suspension order during the ensuing cancellation proceedings. Economic impacts are therefore separately evaluated for the 3 1/2 month period allocated for an emergency suspension proceeding as well as for the two years which may be required for a cancellation proceeding.

**/ The Agency's analysis is based on information from a number of sources including RPAR rebuttal comments received by the Agency from registrants, users and other parties during the RPAR process; and the USDA-States-EPA 2,4,5-T RPAR Assessment Report (February 15, 1979) as well as other relevant data. Although the 2,4,5-T Report attributes a role to EPA, the final report has neither been completely reviewed nor approved by EPA. Therefore, although the Agency has relied on some portions of the report, it cannot and does not wish to adopt all portions of the report as reflecting the Agency position on matters discussed herein.

The non-crop uses of silvex include those it has in common with major uses of 2,4,5-T (forestry, pasture, and rights-of-way), as well as home and garden, and commercial/ ornamental turf and aquatic weed control/ditch bank. (Rangeland is not included). In addition, the Agency has evaluated the economic effects of emergency suspension of these uses - i.e., the consequences of silvex not being available for these uses for the duration of an emergency suspension (3 1/2 months).

Domestic usage of silvex is estimated to be about 2.8 to 3.3 million pounds. Commercial/ ornamental turf and home and garden uses of silvex are the largest volume uses, comprising more than 50% of domestic usage. Aquatic weed control/ditch bank usage accounts for about 8% of annual

usage. Other uses, primarily pasture, account for about 10% of use. The proposed suspended uses of silvex account for about two-thirds of its annual usage. The major remaining uses are rangeland, rice, and sugarcane.

Economic impacts of suspending forestry, pasture, rights-of-way, and non-crop usage of silvex during a two-year period, generally were estimated by assuming all registered alternatives are available, except 2,4,5-T which is also subject to suspension. The analysis generally provides qualitative estimates of impacts since data are not available to support precise quantitative estimates.

Economic impacts during a suspension would depend upon the treatment options actually selected by users. For many, use of silvex during 1979 and 1980 would be optional (i.e., could be delayed to a later year). Other users might choose to use alternatives immediately.

The Agency's analysis indicates that a two-year suspension of silvex non-crop uses would not significantly affect U.S. production or prices of any commodities or services in affected sectors. Economic impacts of the suspension would be minor in most cases, even at the local/ regional level.

The major economic significance of suspending silvex is that it would not be available for more extensive use on forest and pasture sites as a 2,4,5-T substitute. Silvex

usage on those sites could increase significantly in the event of suspension of 2,4,5-T on those sites because silvex is an economic alternative for 2,4,5-T in many instances.

Economic impacts during the 3 1/2 month emergency suspension proceeding would be negligible. Any silvex treatments scheduled for this period could be delayed without affecting the efficacy of the treatments or cost to users.

The economic impacts of suspending each individual non-crop use of silvex, including those it has in common with 2,4,5-T, are discussed below.

(1) Forestry

Silvex now appear to be used on a rather limited scale in forestry. Bureaus of the U.S. Department of Interior (USDI) and the U.S. Forest Service (USFS) have used silvex in the past year. A USDI policy memorandum (June 12, 1970) prohibited use of 2,4,5-T and restricted the use of picloram, but did not include silvex on either prohibited or restricted lists. Nonetheless, USDI use of silvex appears to have been discontinued during 1977. However, as much as 30,000 acres (up to 50,000 pounds a.e.) were treated annually by BLM during the early to mid-1970's. Forest Service use has declined and currently involves very small quantities (less than 500 pounds a.e.) Some silvex could be used by non-govermental users, but no documentation of such usage is available.

Silvex can be used at either or both of two stages in the production*/ of conifers: (1) preparing sites for reforestation and (2) releasing young trees from hardwood competition. Each operation is undertaken once in the 50

*/ Silvex is sometimes used for other forestry herbicide operations, including rehabilitation or species conversion, fuel break maintenance, and timber stand improvement. The major forestry uses of silvex are site preparation and release, which are the focus of this analysis.

year cycle of a softwood stand. Silvex, as well as other chemical and non-chemical control methods, may be used individually or in combination for site preparation and release.

Use of silvex for site preparation is not critical although it is cost effective. Several other chemicals, as well as non-chemical methods, are also effective for site preparation. Picloram and 2,4-D, sometimes combined, are the most effective substitute chemicals. 2,4-D costs less than silvex but controls a more limited spectrum of weeds and often has to be used more frequently, thus resulting in higher costs than a single silvex treatment. In the past, 2,4,5-T has been preferred to silvex for site preparation because it controls a wider variety of hardwoods.

Because the release (weeding) operation is conducted after the seedling trees are in place, a selective herbicide which will not harm the seedlings is preferred. This is particularly true for pine; silvex provides control of many hardwood competitors; however it also can damage pine seedlings. As a consequence of its lack of selectivity silvex has not been extensively used for release treatments. Its use has been limited to non-pine conifer stands in the west and fir-spruce stands in the Northeast.

In both agencies, costs have already been increased by $20-$200/acre due to the use of release methods other than silvex and 2,4,5-T. Site preparation continues at cost increases of $10-$40/acre using picloram/2,4-D and other chemicals on those areas which require herbicide controls. Release costs in Washington and Oregon are $20-$50/acre for substitute chemical control. Manual control, when used, increases costs about $60-$100/acre more than silvex.

USDI is presently reviewing the department policy regarding pesticide use and is considering adding silvex to the list of prohibited chemicals. USDI decisions regarding 1979 plans for use of silvex are pending EPA decisions, and alternative plans have been developed for vegetation management without silvex.

The suspension of forestry uses of silvex for either 3 1/2 months or two years would not have any significant current economic impact because the chemical is not now in use. The prinicipal potential users, USDI and USFS, have already discontinued use. The only significance of the

silvex suspension for forestry use is that it would not be available as a substitute for 2,4,5-T.

(3) Rights-of-Way

Silvex is used to control woody and herbaceous plants on vegetated rights-of-way (railroad, highway, electric transmission, and pipeline) which could hamper the use of the system (weeds encroaching on highways) threaten the system's equipment, and/or interfere with inspection and maintenance of the system.

Manual and mechanical methods are the most common control practices on rights-of-way acreage. Combining chemical and non-chemical control methods is common as is use of herbicide combinations to enhance their effectiveness and expand the spectrum of plants to be controlled in a single application.

Chemical treatment uses a variety of chemicals, including phenoxy herbicides. Usage of silvex for rights-of-way vegetation control is minimal, e.g., less than 2% of rights-of-way firms use it.

If silvex is not available, users can be expected to treat with other herbicides. Dichlorprop, 2,4-D, and picloram mixed with 2,4-D are all cheaper than silvex. Several alternatives control more species than silvex, and equivalent control may be achievable at less cost. No significant negative economic impacts could be expected from a two-year suspension of this use. Economic impacts during a 3 1/2 month emergency suspension would also be insignificant.

(3) Pasture

The phenoxy herbicides (2,4-D, 2,4,5-T and silvex) are registered for the control of many woody and herbaceous weeds on pasture. Silvex is generally more effective for woody plant control than 2,4-D but controls a narrower spectrum of weeds than 2,4,5-T.

Current silvex usage on range and pasture is apparently small enough that no reliable estimates of use have become available. No more than 500,000 pounds active ingredient are used annually. Most of this amount is probably used on range, although states such as Minnesota, Virginia, and New England states recommend silvex for control of some weeds in pasture. In Massachusetts, about 9,000 pasture acres are treated with silvex annually, but pasture usage in other states has not been reported. Silvex was not considered by the 2,4,5-T Assessment Team to be an alternative to 2,4,5-T for pasture or fencerow applications because of its relatively narrow spectrum of control.

Brush control with herbicides on pasture and along pasture fencerows is usually accomplished by spot treatment. Presumably, silvex is also applied in this manner when it is used.

Since other chemicals, e.g., picloram, dicamba, 2,4-D, are generally preferred to silvex for pasture use, farmers who currently use silvex would presumably adopt these alternative herbicides.

No yield or production effects would occur during a two year suspension. For individual farmers using silvex, alternative controls might be more expensive. If so, these farmers' income will be reduced by the amount of the cost-of-control increase. Such effects will be nominal in most cases. There would be no impacts on consumer prices or the general economy. Agricultural income may be reduced by an immeasurably small amount. In view of the limited economic impacts from a two year suspension period, economic impacts during the 3 1/2 months required for an emergency suspension proceeding would be of no significance.

(4) Commercial/Ornamental Turf

Ornamental turf includes golf courses, athletic fields, parks, playgrounds, highway turf, and turf farms for purposes of this analysis. Of these, golf courses are the major consumer of herbicides used to control broadleaf turf weeds.

Precise current estimates of silvex use on turf are not available but annual usage could be as high as 2 million pounds active ingredient. Combinations of 2,4-D, MCPP, and dicamba are readily available and effective treatments for clover and chickweed which are major broadleaf weed pests. In golf courses, these chemicals are common control treatments for these pests. Data on other turf uses are not available.

Without silvex, users will shift to combinations of 2,4-D, MCPP, and dicamba to control broadleaf weed

pests. Treatment costs with silvex, silvex combinations, alternatives, and combinations of alternatives vary depending on region, target weed species, application rates, formulations, and package size. Material costs for silvex and dicamba are comparable at $7.50 per acre. Silvex combined with 2,4-D is about $1 per acre more expensive than MCPP, MCPP + 2,4-D, and 2,4-D + dicamba. Combinations of MCPP/2,4-D/dicamba are about $4.50 to $14.50 per acre more expensive than silvex/2,4-D mixtures. On the average, alternatives are about $3.50 per acre more expensive than silvex and silvex mixtures.

For individual turf managers, these control cost increases will be nominal. Golf courses, for example, spend $80-$90 per acre for turf maintenance which includes chemical fertilizers, fungicides, herbicides, and insecticides, but excludes irrigation, mowing, and other direct costs. Thus, increased broadleaf weed control costs of $3.50 per acre could increase maintenance costs by about 4 percent. Economic impacts during a two year suspension would not be adverse to the overall commercial/ornamental turf sector.No economic impacts are anticipated during the 3 1/2 month emergency suspension proceeding. Most treatments scheduled during this period could be delayed without causing significant control problems or increasing user costs.

(5) Home and Garden

Most of the herbicides used by the homeowner in the U.S. are for control of broadleaf weeds and grass pests in lawns. At least three-fourths of U.S. homeowners do not use any herbicides. Liquids are more popular than granular forms in terms of quantities used and dollar sales. Several hundred thousand pounds of silvex are used annually on home lawns.

Silvex is most commonly used with 2,4-D, MCPP, and dicamba to control species resistant to 2,4-D (i.e., chickweed, clover, spurge and henbit). Based on label claims and state recommendations, combinations of 2,4-D, MCPP, and dicamba would be equally effective.

Homeowners would shift to products containing 2,4-D, MCPP, and dicamba in the event of a silvex suspension. These alternatives are effective, readily available, and comparably priced. Thus, homeowner adjustments for either 3 1/2 months and/or 2 years suspension would be nominal.

(6) Aquatic Weed Control/Ditch Bank

Aquatic weeds are a nuisance in water bodies used for recreation and in farm ponds used for watering livestock. Major users of herbicides for aquatic weed control are government and private recreational organizations and farmers. Government purchases of aquatic herbicides account for nearly half of annual sales. Private recreation organizations account for more than a third and farmers the remainder.

Silvex and a mixture of silvex and endothall are registered for use in aquatic weed control in ponds, lakes, marshes, and shorelines. Silvex controls submerged, emerged, and floating types of flowering plants. Essentially all weeds controlled by silvex are sensitive to various other major aquatic herbicides, including 2,4-D, diquat, endothall, and dichlobenil. Silvex, 2,4-D, and diquat exhibit similar herbicidal activities in aquatic sites.

Silvex is also applied to drainage ditch banks and canal levees. Particular target weeds include the phyreatophytes, various exotics, and other woody plants such as rubber and willow trees (Loeser, 1975; Baker, 1975). There appear to be no viable alternative chemical controls for some plant pests such as the phreatophytes and some exotics (Loeser, 1975). However, there are many other chemicals registered that are effective on many species found along ditch banks and canal levees.

For most uses of silvex, 6 pounds a.i./acre per foot are applied in late spring to early summer. Approximately 240,000 pounds of silvex were used in 1972 for water management purposes (von Rumker et al. 1974). This estimate includes silvex used in static water areas such as recreational sites, reservoirs, settling ponds, and ditch banks. At an assumed application rate of 6 pounds of silvex per acre, approximately 60 thousand acres of static water and ditch banks were treated in 1972.

Consumption of silvex for weed control in stationary water areas is not critical due to the availability of effective chemical alternatives including 2,4-D, diquat and dichlobenil. Also, the Argentine flea beetle is an effective biological control of alligator weed when used in an IPM program with silvex or 2,4-D.

Economic effects of suspending aquatic/ditch bank users of silvex for 3 1/2 months or 2 years would be nominal because effective, economical alternatives are available. There would not be a significant economic burden on users.

V. PROCEDURAL MATTERS

This order directs the emergency suspension of the forestry, rights-of-way, pasture, home and garden, aquatic weed control/ditch bank, and commercial/ornamental turf uses of silvex. Registrants affected by emergency suspension actions may request an expedited hearing before the Agency. This section explains how to request an expedited hearing, the consequences of requesting or not requesting an expedited hearing, and the procedures which govern an expedited hearing in the event one is requested.

A. Procedures for Requesting a Hearing

(1) Who May Request a Hearing and When the Request Should Be Made

Registrants of silvex products registered for the forestry, pasture, rights-of-way, home and garden, aquatic weed control/ditch bank, or commercial/ornamental turf uses

of silvex may request a hearing on these specific registered uses of silvex within five days after receipt of this opinion and order.

(2) How to Request a Hearing

Registrants who request a hearing must follow the Agency's Rules of Practice Governing Hearings (40 CFR, Part 164). These procedures specify, among other things: (1) that all requests for a hearing must be accompanied by objections that are specific for each use for which a hearing is requested [40 CFR 164.121(a) and 164.123(b)] and (2) that all requests must be filed with the Office of the Hearing Clerk within the applicable five (5) days [40 CFR 164.121(a)]. Failure to comply with these requirements will automatically result in denial of the request for a hearing.

Requests for hearings must be submitted to:

Hearing Clerk (A-110)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

B. Consequences of Filing a Hearing Request

Under FIFRA Section 6(c)(3) the emergency suspension order becomes effective immediately and, unless stayed, continues in effect until completion of the expedited hearing and issuance of a final order of suspension. The statute provides that where an administrative hearing is requested, the emergency order is subject to District Court review on the emergency finding. The final suspension order

issued by the Administrator after a hearing may keep the suspension in effect, modify it, or terminate it. A final suspension order issued following a hearing is then reviewable in the Court of Appeals.

The statute provides that if a hearing is requested on the Administrator's emergency suspension actions regarding silvex before the end of the five-day notice period, the hearing stage is to begin within five days after receipt of the request, unless the registrant and the Agency agree that it shall begin at a later time. No party, other than the registrant and the Agency, is to participate, except that any person adversely affected may file briefs within the time allowed by the Agency's rule. Hearings on emergency suspension, like hearings on ordinary suspension, are subject to the provisions of subchapters II of Title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. The presiding officer has ten days from the conclusion of the presentation of evidence to submit recommendations to the Administrator, who in turn has seven days to issue a final order on the issue of suspension.

C. Consequences of Not Filing a Hearing Request

Under the statutory scheme, if there is no request for a hearing on the Administrator's suspension actions within the five-day notice period, the emergency suspension order becomes a final suspension order, which remains in

effect until the conclusion of the cancellation proceedings, unless modified or vacated sooner (40 CFR 164.130). Court review of an emergency suspension order, including the special review before the District Court discussed in Part II, is available only if an administrative hearing has been requested within the applicable five-day period [FIFRA Section 6(c)(2), 6(c)(3)].

D. Supplementary Procedures

EPA's Rules of Practice for expedited hearings are set forth at 40 CFR Part 164, Subpart C. I do not know if a hearing will be requested on these suspensions. If it is, however, I am establishing the following procedures to supplement the existing regulations in governing its conduct.

1. A deadline is being established for the completion of all hearing procedures and the rendering of a recommended decision under 40 CFR 164.121(j). That deadline is 90 calendar days from the first prehearing conference, which shall be held in accordance with the time requirements described below.

2. I am naming certain EPA employees to serve as a hearing panel in any hearing arising out of this notice (see Appendix A).

I am naming certain additional persons to be available to provide technical advice and staff support to the hearing panel (see also Appendix A). If questions arise at the

hearing which persons in this category are uniquely qualified to assess, they may be called on to serve on the panel either in addition to, or in substitution for, the three panel members named above.

The panel will conduct the hearing and submit a recommended decision to me under 40 CFR Section 164.121(j). None of the persons named above is subject in the normal course of their duties to the supervision or direction of any employee or agent of EPA who is a member of the Agency trial staff named below. See 5 U.S.C. Section 554(d)(2).

Since 5 U.S.C. Section 554(d)(1) provides that those presiding at adjudicatory hearings may not "consult a person or party on a fact in issue [in the course of preparing their decision] unless on notice and opportunity for all parties to participate," neither myself nor my appellate staff will consult with the panel or its supporting staff on any matters involving this case from the date of notice until a recommended decision is issued. Members of my appellate staff are listed in Appendix A. We will conduct an independent review of the questions presented on appeal of any recommended decision. However, in doing this we will feel free to consult with the hearing panel and the support panel, since they will have conducted the initial proceedings and brought expert knowledge to evaluating the record.

The following Agency bureaus or divisions, and ther staffs, are designated to perform all investigative and prosecutorial functions in this case: Office of the Deputy Administrator*/, Office of Toxic Substances, the Office of General Counsel, and the Office of Enforcement.

From the date of this notice until any final decision, no member of the hearing panel, its support staff, my appellate staff, or myself, shall have any ex parte contact with any trial staff employees, or any other interested person not employed by EPA, on any of the issues involved in this proceeding. However, persons interested in this case should feel free to contact any other EPA employee, including both trial staff and persons not explicitly named as panel members or assistants, with any questions they may have.

3. I am directing the hearing panel to proceed as follows to streamline proceedings in this case:

a. My findings on imminent hazard and emergency for suspended uses of silvex together with supporting

*/ The Deputy Administrator may properly be included in the trial staff since the prohibitions of 5 U.S.C. Section 554(d) do not apply to "the agency". Her inclusion is necessary if guidance on general policy matters is to be available to the trial staff and, to free a high agency official to talk to outside interested persons about the questions involved without the constrains otherwise imposed by the ex parte provisions of the APA and the Government in the Sunshine Act. The Deputy Administrator will take no part in the detailed work of preparing and presenting the Agency's case.

information are in my opinion and order, which is available for inspection in the Office of the Hearing Clerk. Additional supporting information, including references cited in the opinion and orders, is also available for inspection in the Office of the Hearing Clerk. Together these documents constitute the Agency record in this matter.**/ EPA has also attempted to put this information in perspective through a narrative summary and analysis.

b. The scheduling of any hearing, particularly in its earlier stages, involves a balancing between the need to conduct an expeditious hearing and a concern that the hearing not proceed too far before the identity of those registrants requesting a hearing is established. In arranging for the first prehearing conference, I have attempted to accommodate both interests. The hearing panel shall convene the first prehearing conference within five days after receipt of the last request for a hearing by a registrant or 15 days after the issuance of my opinion and order, whichever comes earlier. The 15-day maximum should ensure that all registrants wishing to participate in the hearing have been given ample time to file a hearing request after receiving notification of my suspension actions.

**/ Some of the documents in the record may be entitled to confidential treatment under FIFRA Section 10, as amended. Parties to the hearing may have access to such documents, if appropriate protective arrangements are made. See also the footnote to this Order concerning confidentiality of data in Section IV.A.(1)(a)(i).

c. Within ten days from the first prehearing conference, any person requesting a hearing shall submit focused written comments on this opinion and order consisting of a counterstatement of proposed findings on the issue of imminent hazard presented by silvex together with supporting information. A narrative summary explaining its bearing on the case should also be included.

d. The Agency trial staff shall have seven days thereafter to file supplemental information and comments.

e. Within five calendar days from the filing of any supplemental information by the Agency staff, the panel shall convene a second prehearing conference. At this conference all parties shall appear prepared to present arguments on the signficiance and relevance of the material already presented. This prehearing conference shall also hear all requests for oral presentation of direct evidence and cross-examination, and the reasons supporting them. At this time each party shall present the names of witnesses available for cross-examination on the matters the party is putting into issue. The party may list documents (or portions thereof) on which the potential witness is available for cross-examination in lieu of filing a formal witness statement.

f. Within five days after the prehearing conference is over, the panel shall issue a hearing order setting the schedule for oral presentation of witnesses and cross-examination.

(1) Requests for oral presentation of direct testimony shall be granted only if it is demonstrated that the testimony can be presented meaningfully only in that form; in all other cases, direct testimony shall be in writing.

(2) Requests for cross-examination shall be granted only if all of the following showings are made:

i. The request concerns factual matters. Cross-examination will not be granted on matters of policy or law.

ii. The factual matters are legitimately in dispute in light of the record.

iii. The factual matters are material to the decision to be made.

iv. Cross-examination is the most efficient way of resolving the dispute over these factual matters (as opposed to such alternatives as production of further information, or informal conferences).

v. There is a reasonable expectation that cross-examination will resolve the issue of material fact in a way likely to influence the final decision.

g. The testimonial phase of the hearing shall begin three days after issuance of the order setting the hearing schedule. At the hearing, the panel shall take an active role in the development of the record through questioning of witnesses and by issuing procedural orders where necessary.

h. At the end of the initial testimonial phase, the hearing panel may permit the introduction of additional information designed to rebut the contentions made by opposing parties.

i. The panel may revise any of the procedural provisions of this notice other than the overall 90-day deadline for rendering a recommended decision, the time for which starts running after the first prehearing conference.

A discussion of some aspects of these procedures follows:

(1) Deadlines

Deadlines for completing proceedings under FIFRA have been twice endorsed by the National Academy of Sciences [National Academy of Sciences, Decision Making in the Environmental Protection Agency, Vol. II, p. 84 (1977); National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment, p. 30 (1975)].

In addition, Congress has demonstrated a concern for speedy action where suspensions based on a potential threat to human health are concerned. It has required a

hearing on such a suspension to begin five days after it is requested*/, and has allowed ten and seven days respectively for preparation of the initial and final decisions once the hearing is over [FIFRA Section 6(c)(2)]. FIFRA was amended in 1975 to require consultation by EPA with the Department of Agriculture and a scientific advisory panel before taking action in many cases; suspensions based on human health grounds, however, were exempted from those requirements to allow speedy action where speedy action was desirable [121 Cong. Rec. H 9895-96 (daily ed. Oct. 9, 1975); 121 Cong. Rec. Section 19820-21 (daily ed. Nov. 12, 1975)].

Deadlines for completing the hearing have been imposed in prior suspensions. See, e.g., In re: Vesicol Chemical Co., et al., 41 F.R.7552, 7553 (Feb. 19, 1976) [Notice of Intent to Suspend Heptachlor and Chlordane], and In re: Dibromochloropropane, 42 FR 48915 (Sept. 26, 1977). [Notice of intent to suspend and conditionally suspend registrations of pesticide products]. The requirements set forth in this order simply carry forward that practice.

(2) Use of a Panel

Despite the need for speedy action, the issues involved in suspension are complex. Under the statute, a

*/ I do not regard the procedures set forth below as inconsistent with this directive. What concerned Congress was plainly that the hearing stage of Agency decision-making begin promptly, not that the oral hearing itself start unconditionally in less than a week. To interpret the law otherwise would forbid the use of such accepted aids to efficient decisions as prehearing conferences in precisely the cases where efficiency is most required.

judgement of "imminent hazard" must be based on consideration of costs and risks of all types [FIFRA Sections 2(l), 2(bb)]. Given the necessary time constraints and the preliminary nature of suspension as a remedy, factual certainty may be elusive. "[T]he function of the suspension decision is to make a preliminary assessment of evidence, and probabilities, not any ultimate resolution of difficult issues" [Environmental Defense Fund, Inc. v. EPA, 510 F.2d. 1292, 1298 (D.C. Cir. 1975), quoting from Environmental Defense Fund, Inc. v. EPA, 465 F.2d. 528, 537 (D.C. Cir. 1972)].

Arriving at even such a preliminary assessment can present formidable difficulties. Considering risks, questions can arise concerning the dispersion and persistance of the pesticide in the environment and certain parts of it, the conduct of animal feeding studies, the meaning of those studies for human health, the validity of relevant epidemiological studies, the reliability of using known human exposure from one use pattern as a predictor of potential human exposure in other use patterns, and finally on what the upper and lower boundaries of any risks may be and how firmly they are established. Considering benefits, questions can be raised about the extent of use, the availability, practicality, and effectiveness of substitutes both now and in the future, and the range of the probable economic impacts of a temporary ban on the pesticide, or some use of it, in the light of all these factors.

The job will be easier and better performed, if I am allowed to rely directly on the talents of EPA employees with expert knowledge of the technical fields involved and with the professional ability to assess problems arising in them. I believe it is for this reason that Congress has provided that those presiding over suspension hearings need not be hearing examiners*/.

(3) Conduct of the Hearing

Overuse of cross-examination and courtroom formalities, I believe, has made many FIFRA proceedings far longer than was consistent with any rational purpose. The overwhelming bulk of legal analyses by those who have studied the problem, and EPA's own experience demonstrate that scientific and economic issues can be clarified by the exchange of written material far more efficiently than through courtroom hearings. I am directing that written submissions be used here to focus the issues in an attempt to implement those lessons. At the same time, particularly where Congress has explicitly called for formal hearings, the accompanying rights to reasonable cross-examination and oral presentation must be preserved.

*/ The fact that more than one person will preside is of no legal significance. Even when 5 U.S.C. Section 556 requires a hearing to be presided over by an examiner (or a person representing the Agency), it also specifies that "one or more" of those qualified may preside.

All three elements of these supplementary procedures are meant to work together. The use of a panel will ensure that expert knowledge is indeed brought to the task of making a decision. The provision for preliminary written submissions will allow that panel to screen the issues and narrow the formal part of the hearing down to those that are legitimately in dispute and suited to adjudicatory resolution. Finally, setting a schedule for decision will help ensure that the potential gains in efficiency represented by the first two reforms are realized in practice.

Douglas M. Costle
Administrator

Dated: FEB 28 1979

APPENDIX A

HEARING PANEL

Charles Gregg, Chairperson
William Brungs
Robert Coughlin

TECHNICAL SUPPORT PANEL

Robert Chapman, M.D.
Neil Chernoff
Arnold Kuzmack
Dr. James Lichtenberg

ADMINISTRATIVE APPELLATE PANEL

Ronald L. McCallum
Charles R. Ford
Dr. Edwin H. Clark
Ms. Mary Ann Massey
Dr. Richard M. Dowd
Dr. Stephen J. Gage